

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY
CIVIL ACTION NO 16-MD-2738 (FLW) (LHG)

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IN RE JOHNSON & JOHNSON : DAUBERT HEARING
POWDER PRODUCTS MARKETING, : JULY 23, 2019
SALES PRACTICES. : VOLUME 2
----- :

CLARKSON S. FISHER UNITED STATES COURTHOUSE
402 EAST STATE STREET, TRENTON, NJ 08608

B E F O R E: THE HONORABLE FRED A. L. WOLFSON, USDJ

A P P E A R A N C E S:

BEASLEY ALLEN, ESQUIRES

BY: P. LEIGH O'DELL, ESQUIRE (ALABAMA)

MARGARET M. THOMPSON, ESQUIRE (ALABAMA)

JENNIFER K. EMMEL, ESQUIRE (ALABAMA)

-and-

MOTLEY RICE, ESQUIRES

BY: DANIEL R. LAPINSKI, ESQUIRE (NEW JERSEY)

-and-

DALIMONTE RUEB STOLLER, ESQUIRES

BY: JOHN M. RESTAINO, JR., ESQUIRE (CALIFORNIA)

On behalf of Plaintiffs Steering Committee

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JULIE L. TERSIGNI, ESQUIRE (NEW JERSEY)

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SKADDEN, ARPS, SLATE, MEAGHER & FLOM, ESQUIRES

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(Continued.)

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A P P E A R A N C E S C O N T I N U E D

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On behalf of Defendant Johnson & Johnson

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On Behalf of Defendant Personal Care Products Council

M O R N I N G S E S S I O N

(In open court.)

THE DEPUTY CLERK: All rise.

THE COURT: Thank you.

Everyone may be seated.

Ready to start?

MS. SHARKO: Yes. Thank you, Judge.

Defendant Johnson & Johnson calls Dr. Benjamin
G. Neel.

BENJAMIN G. NEEL, called as a witness on behalf of
the Defendant, having been first duly sworn, testified
as follows:

DIRECT EXAMINATION

BY MS. SHARKO:

Q. Dr. Neel, welcome back to New Jersey.

A. Thank you.

Q. Where did you grow up?

A. I grew up in the Philadelphia area. When I was
in eighth grade we moved to Cherry Hill. South
Jersey.

Q. What is your job generally?

A. I am the director of the Laura and Isaac

1 Perlmutter Cancer Center at NYU Langone Health, and I
2 run a 13-person research laboratory at NYU School of
3 Medicine as a Professor of Medicine.

4 Q. To what has your life been dedicated, Dr. Neel,
5 your professional life?

6 A. My professional life has been dedicated to the
7 study of cancer, biology, and, more specifically, to
8 understanding cell signalling, which is the mechanism
9 by which cells receive signals from the outside world
10 and how that is abnormal in cancer cell, and more
11 recently, on mechanisms of ovarian cancer
12 pathogenesis.

13 Q. Now, the Judge has your CV, and it is in
14 evidence, but let's just go through a couple of
15 highlights. I have it on the slides to make it go
16 quicker.

17 You talked about your current position. Some
18 of the past positions you've had include having a
19 Chair and being a Full Professor of Medicine at
20 Harvard Medical School and being the director of
21 Princess Margaret Hospital Center in Toronto, which is
22 the major cancer center up there. Correct?

23 A. It's the largest cancer center in Canada.

24 Q. Does the slide summarize some of your major
25 research interests?

1 A. Yes.

2 Q. Now, you have over 200 peer reviewed
3 publications?

4 A. Yes.

5 Q. You have been cited more than 45,000 times by
6 the scientific community?

7 A. Yes.

8 Q. Does this slide list some of the editorial
9 boards of major journals that you have been involved
10 with?

11 A. Yes. Including the two most prominent cancer
12 journals currently.

13 Q. What are those?

14 A. Cancer Cell and Cancer Discovery.

15 Q. Does this slide list a few of the honors and
16 awards you've earned as a faculty member?

17 A. Yes.

18 Q. Does it include some of your key speaking
19 engagements and meetings that you organized?

20 A. Yes.

21 Q. You have done more speeches than the two or
22 three listed on here?

23 A. Yes. Ms. Sharko, actually, last week I was the
24 keynote speaker at the FASEB Kinase Meeting in Palm
25 Springs; and tomorrow I will be leaving for a major

1 meeting in Tokyo.

2 Q. What are the areas of focus for you and your
3 team in the research lab?

4 A. So about half of my lab works on cell signalling
5 in normal cells and how that is regulated in cancer
6 with a particular focus on tyrosine phosphatase, and
7 the other half works on generating new models of
8 ovarian cancer and the cell of origin of ovarian
9 cancer.

10 Q. Are you doing anything with the mouse and
11 ovarian cancer currently?

12 A. Yes. The new models. I should have been more
13 specific, our new mouse models of ovarian cancer. So
14 we basically introduce the same genetic changes that
15 are found in human ovarian cancer. We model them in
16 mouse fallopian tube organoids, and we can study their
17 properties in cell culture and we can take the same
18 cells and inject them in the ovarian bursa and test
19 whether they generate ovarian cancer.

20 Q. Dr. Neel, has the scientific community's
21 knowledge and understanding of ovarian cancer changed
22 since the time you earned your degrees in the 1980s?

23 A. Yes. Actually, I tell my students and post docs
24 nothing is the same today as it was when I was their
25 age, and we have actually learned more about cancer

1 biology in the last 15 years than in all of recorded
2 history before that. We've also learned more I think
3 about the pathogenesis, the molecular pathogenesis of
4 ovarian cancer during that time in the last 15 years
5 than we knew before.

6 Q. Have you written a report in connection with
7 this litigation?

8 A. I have.

9 Q. And the Judge has a copy of your report. It is
10 in evidence. It is also in the binder in front of
11 you.

12 Are the opinions in your report and your prior
13 testimony and your testimony here today, has all that
14 been expressed or will be expressed to a reasonable
15 degree of scientific and medical probability?

16 A. Yes.

17 Q. And are the opinions that you are going to give
18 here today your own?

19 A. Yes.

20 Q. What are they derived from?

21 A. They are derived from my 40 years of experience
22 in the field of cancer biology including 30 years as a
23 faculty member at the institutions that you had on the
24 slide and that are in my CV, and also a review of the
25 relevant literature concerning the topic and a review

1 of the expert reports of some of our experts and some
2 of the plaintiffs experts and the depositions of some
3 of them.

4 MS. SHARKO: We'll move on to substantive
5 areas, unless, Judge -- do you have any questions?

6 THE COURT: No.

7 BY MS. SHARKO:

8 Q. Okay. Cancer. Topic One.

9 Dr. Neel, what is cancer?

10 A. Cancer is a disease of what we have called the
11 genome, and that's the collection of genes that we
12 have in our body, and it consists of different types
13 of mutations affecting usually six to eight different
14 types of genes that take a normal cell and change it
15 into a cancer cell.

16 Q. Are there different types of mutations that can
17 occur in a cell to cause cancer?

18 A. Yes.

19 Q. What are they and what do they do?

20 A. As shown on this slide, there are three general
21 categories of mutations that are found in cancer cells
22 and they contribute to cancer: point mutations -- so
23 DNA is like an alphabet, and it's like reading a book.
24 There are different letters, and the precise order of
25 the letters determines the genetic code and also

1 determines the regulation of the genes that are
2 encoding the genetic code. If you change the letter
3 in a single position -- for example, if you change an
4 A to a T or G to a C, that's a point mutation.

5 These point mutations can have two different
6 types of consequence. They can cause a gain of
7 function in a protein. They can increase the function
8 of an enzyme, for example, or if they occur in a
9 regulatory sequence, they can increase the expression
10 of a gene of interest.

11 Alternatively, if they occur in a structural
12 part of a protein, they can cause a loss of function
13 or a decrease in that particular cell activity.

14 The second general type of mutation is what we
15 call a structural variant, and that involves a change
16 in the structure of chromosomes. That can be, for
17 example, a translocation, and a translocation occurs
18 when chromosomes break and they rejoin
19 inappropriately. For example, the classic example of
20 a translocation is the breakage of chromosomes 9 and
21 22; and the rejoining of chromosome 9 to 22 to form
22 the Philadelphia chromosome, which causes chronic
23 myelogenous leukemia or CML.

24 THE COURT: Ms. Sharko, do you have a copy of
25 the PowerPoint?

1 MS. SHARKO: Yes.

2 (Pause.)

3 A. So when the Philadelphia chromosome, for
4 example, is created, that result is in a fusion
5 protein, and in that case a piece of one protein is
6 joined inappropriately to the piece of another
7 protein, and it makes that protein stay on all the
8 time; its activity stays on all the time.

9 You can also have an inversion which alters
10 the structure of a chromosome. Both translocations
11 and inversions can lead to insertional activation or
12 inactivation of genes.

13 The third kind of cancer associated
14 abnormality is called a copy number abnormality. A
15 copy number abnormality means an increase or a
16 decrease in the number of copies of a gene or genetic
17 region. Amplification means too many copies, more
18 than the usual number of copies, more than two copies.
19 Deletion means a loss of one or more copies of a gene.

20 Those are the three major categories of
21 mutations that are associated with cancer.

22 Q. Now, if a person develops a mutation, does that
23 mean that the person is certain to go on to develop
24 cancer?

25 A. No.

1 Q. So in your report at the Bates stamp number
2 pages 9 and 10, you discuss the process of how cancer
3 in general disrupts normal cell regulation. Is this
4 slide and what will follow a fair and accurate
5 representation or summary of how some of the ways in
6 which cancer disrupts normal cell regulation?

7 A. Yes.

8 Q. Could you explain that a little please?

9 A. Sure.

10 As you can see, on the left-hand part of the
11 slide normal cells have a variety of characteristics.
12 They typically don't grow without growth factor
13 signals. They need certain signals to grow. They
14 also are able to respond to other signals that are
15 called growth inhibitory signals. They self-destruct
16 or undergo, a term you heard yesterday, apoptosis,
17 when they suffer DNA damage that is unrepairable or
18 other types of cellular insults that are unrepairable.

19 They also divide typically only a limited
20 number of times. They replicate or reproduce their
21 genomes, their genes, with high fidelity. They do not
22 send signals to surrounding blood vessel cells to make
23 new blood vessels, a process known as angiogenesis.
24 They typically are located within a defined region of
25 your body, so a cell in your colon doesn't end up in

1 your liver.

2 When normal cells express abnormal proteins,
3 they can display pieces of these abnormal proteins to
4 the immune system and your immune system can eliminate
5 the cells.

6 Finally, they typically have defining
7 characteristics that make them look unique. A breast
8 cell looks different than a stomach cell, for example.
9 We call this the differentiated state of the cell.

10 Q. So, now, bring on the mutations, and there are
11 numerous ways that mutations can change cells. Fair
12 to say?

13 A. Right. The combination of mutations that occur
14 in cancer result in the disruption of all of the
15 processes that I listed on the left-hand part of the
16 slide and just discussed and results in transformation
17 to a cancer cell.

18 Q. Now, reactive oxygen species commonly known as
19 ROS, what are they?

20 A. Cells have processes that are normal that
21 generate oxygen or nitrogen radicals. For example,
22 cells, when they respond to certain growth factors,
23 generate hydrogen peroxide, which is one example of a
24 reactive oxygen species. Your mitochondria, which are
25 part of your cells that carry out respiration and

1 generate energy, they also generate reactive oxygen
2 species as part of normal metabolism. So ROS are
3 produced normally in cells. Also, under certain
4 disease conditions or stress conditions, there can be
5 excess ROS produced. So you can have both normal ROS
6 production and abnormal ROS production in cells.
7 That's what reactive species are.

8 Q. Is the generation of reactive oxygen species
9 necessarily or always a bad development for the human
10 body?

11 A. No. As I just tried to explain, part of normal
12 cellular physiology is the production of reactive
13 oxygen species. Cell signalling is impaired in
14 certain cases if you block the production of reactive
15 oxygen.

16 Q. We have been using the term "cancer" a lot this
17 morning. Is cancer one single disease?

18 A. No. Actually, one of the major advances in the
19 last 20 years has been the sequencing of, first, the
20 normal human genome, and multiple different types of
21 cancer cells, and that's told us cancer is actually
22 many different types of diseases caused by many
23 different types of mutations such as I've already
24 discussed occurring in different cells of origin. So
25 cancer has many diseases.

1 Q. Let's now switch topics and go to ovarian
2 cancer. Is ovarian cancer a single disease?

3 A. No.

4 Q. What are the different types of ovarian cancer?

5 A. So, again, this is also information that has
6 become available over the last -- more available over
7 the last 15 to 20 years. And there is nonepithelial
8 ovarian cancer, and epithelial ovarian cancer. As I
9 understand it, the subject of this litigation is
10 epithelial ovarian cancer. So I won't discuss the
11 non-epithelial forms, and these forms account for
12 90 percent of ovarian cancer anyway.

13 THE COURT: Which accounts for 90 percent?

14 THE WITNESS: Epithelial ovarian cancers. So
15 the epithelial ovarian cancers have been subdivided
16 into two large subcategories: Type I tumors, as you
17 can see on the slide, and these are low grade serous
18 ovarian cancer, mucinous carcinoma, endometrioid, and
19 clear cell carcinoma.

20 Q. So do these two types of tumors have different
21 cells of origin and different genetic mutations that
22 lead to them?

23 A. Yes. You can see on the slide the cell of
24 origin of Type I tumors are often from endometriosis
25 or endometriotic lesions that come from the

1 endometrium in the uterus and are transplanted to the
2 peritoneum, and the mutations that cause Type I
3 tumors, as you can see from the slide, are generally
4 point mutations in genes that are involved in cellular
5 signalling or epigenetic regulation.

6 Q. Let's go to Type II cancers or Type II tumors.

7 A. The Type II tumors are mainly serous high grade,
8 serous ovarian carcinoma, and its relatives. These
9 are all very similar types of tumors, and one of the
10 major discoveries in the last 15 years has been that
11 at least 60 percent of high grade serous ovarian
12 cancers originate in the fimbriae of the fallopian
13 tube. And unlike the Type I tumors high grade serous
14 ovarian cancer or Type II tumors is a copy number and
15 structural variant disease. Its hallmark is genetic
16 or genomic instability.

17 So if I can summarize, the Type I and Type II
18 tumors originate in different cells of origin, and
19 they are caused by different mutations, and they are
20 caused by different mutagenic or mutational processes.

21 Q. I see on the slide under Type II tumors TP53 in
22 several boxes, but I don't see that for Type I tumors.

23 First of all, what is TP53 or a p53 mutation?

24 A. Scientists have a nomenclature. So TP53 is the
25 official human gene name for the gene that encodes a

1 protein called p53. Most of us refer to it as p53,
2 but the official gene name is TP53, and p53 is a
3 particularly important gene in cancer.

4 Q. Why?

5 A. P53 is a hallmark tumor suppressor gene. As I
6 said earlier, there are a gain of function mutations
7 and loss of function mutations in different cancers.
8 Gain of function mutations occur in genes that we call
9 oncogenes. And the loss of function mutations occur
10 in the other kind of cancer-associated gene tumor
11 suppressor genes. P53 is the hallmark tumor
12 suppressor gene and at this time has many important
13 functions in maintaining cell integrity.

14 Q. What is the p53 relationship to the causation of
15 ovarian cancer?

16 A. The Type II tumors essentially all have either a
17 point mutation followed by a deletion in p53 or they
18 have loss of both copies of p53. So p53 mutation or
19 deletion or both is sort of the sine qua non of Type
20 II tumors, and it's also the earliest event in the
21 Type II tumors.

22 Q. Dr. Neel, do you have an opinion to a reasonable
23 degree of scientific and medical probability as to
24 whether talc exposure causes p53 or any other gene
25 mutation?

1 A. Yes.

2 Q. What is your opinion?

3 A. There is no evidence to support that claim.

4 Q. Now, in your expert opinion as a cancer
5 biologist, what is the significance of epidemiologic
6 studies that lump together all the ovarian cancer
7 subtypes?

8 A. I would view them with some skepticism.

9 Q. Why?

10 A. Because as the slide indicates, these tumors are
11 caused in different cells of origin by different types
12 of mutations, and, generally, mutagenic agents cause
13 different types of mutational processes. They don't
14 cause multiple types of mutational processes such as
15 the case for the Type I tumors versus the Type II
16 tumors.

17 Q. Now, let's turn to another one of the
18 plaintiffs' hypotheses.

19 What are MUC-1 antibodies?

20 A. MUC-1 is a mucus glycoprotein that is expressed
21 on fallopian tube cells and other cells, and
22 antibodies against MUC-1 would be antibodies directed
23 against that glycoprotein, directed against MUC-1.

24 Q. Dr. Neel, do you have an opinion to a reasonable
25 degree of medical and scientific probability as to

1 whether the use of talcum powder products increases
2 the risk of ovarian cancer or causes ovarian cancer by
3 prohibiting MUC-1 antibodies as hypothesized by the
4 plaintiffs' experts?

5 A. Yes.

6 Q. What is your opinion?

7 A. There is no evidence to support that claim.

8 Q. Okay. Let's turn to biologic plausibility.

9 MS. SHARKO: Judge, there are more details in
10 his report on some of his opinions, but to save time,
11 we're just covering the highlights.

12 THE COURT: I understand.

13 Q. Biologic plausibility, what is it?

14 A. Biologic plausibility means to me that there is
15 some experimental evidence to support a hypothesis
16 about a potential cause of a cancer.

17 Q. Why is that important particularly in a case
18 like this?

19 A. It's particularly important when the other
20 evidence is relatively inconsistent or weak. For
21 example, when the epidemiological evidence is in
22 conflict and/or the purported effect size of a
23 particular agent is small or relatively small, it's
24 particularly important to have some sort of scientific
25 evidence as to the mechanism by which a particular

1 agent would be proposed to cause the cancer.

2 Q. When you are reviewing papers for scientific
3 journals, is biologic plausibility something you look
4 for?

5 A. Actually, it's everything I look for along with
6 technical credibility. In fact, every paper that I
7 publish is designed to test the biological
8 plausibility of a hypothesis.

9 Q. Is biologic plausibility also one of the several
10 Bradford Hill criteria?

11 A. Yes, it is.

12 Q. Do you need absolute proof of mechanism to have
13 biologic plausibility?

14 A. No, but you need to have some credible
15 scientific evidence supporting the hypothesis.

16 Q. Why do you need more than just a hypothesis to
17 show biologic plausibility?

18 A. A hypothesis without evidence is basically an
19 opinion or speculation.

20 Q. In your opinion, to a reasonable degree of
21 medical and scientific probability, is it biologically
22 plausible that the perineal application of talcum
23 powder products causes ovarian cancer?

24 A. No, not with the present evidence.

25 Q. Now, what does our current understanding of Type

1 I and Type II tumors tell us about whether the
2 plaintiffs' theory here is biologically plausible?

3 A. It's unlikely a single agent would cause both
4 types of tumors because, as I said earlier, both types
5 of tumors initiate in different cells of origin and
6 have different mutagenic processes underlying them.
7 It's also unlikely an agent that has never been shown
8 to be mutagenic would cause these mutations.

9 Q. We talked about biologic plausibility. Let's go
10 to causation.

11 Do you have an opinion to a reasonable degree
12 of scientific and medical probability as to whether
13 the perineal use of talcum powder products cause
14 ovarian cancer?

15 A. Yes.

16 Q. And what is your opinion?

17 A. There is no evidence to support that claim.

18 Q. Now, moving along. Next would be migration.
19 We'll skip over that in deference to other experts so
20 we don't have repetition, and let's go to
21 inflammation.

22 Do ovarian tumors have inflammation associated
23 with them in general?

24 A. Fully blown ovarian cancers -- so if a woman has
25 a fully blown ovarian cancer, those tumors are

1 associated with inflammation. Interestingly, those
2 tumors are associated with different types of
3 inflammation. For example, one woman's tumor could be
4 associated with different types of inflammation than
5 another woman's tumor. This is tumor-associated
6 information. So ovarian tumors are associated with
7 inflammation.

8 Q. Does that mean the inflammation caused the
9 ovarian cancer?

10 A. No. In order to understand or to study whether
11 inflammation causes ovarian cancer, you have to look
12 at the early events in ovarian cancer and ask whether
13 there is any evidence that the early events are
14 associated with inflammation.

15 Q. So what are precursor lesions? Is that the
16 earlier events you are talking about?

17 A. Yes. So precursor lesions are lesions you can
18 see under a microscope either with standard stains or
19 sometimes with specialized immunohistochemical stains.
20 These lesions have been shown by molecular approaches
21 to be the cells that give rise to the eventual fully
22 blown ovarian cancer. So that's what a precursor
23 lesion is.

24 Q. What are STICs?

25 A. STICs stands for serous tubal intraepithelial

1 carcinoma, and STICs are the hallmark of preneoplastic
2 or precursor lesion of high grade serous ovarian
3 cancer. They are an example of a precursor lesion for
4 high grade serous ovarian cancer.

5 Q. What is a p53 signature?

6 A. So p53 signature is thought to be potentially an
7 earlier precursor lesion. So p53 signature means a
8 cluster of cells that stains with an antibody directed
9 against p53, and many times the p53 mutations result
10 in an abnormally stable form of the protein, and that
11 means that it can be detected by an antibody.
12 Typically p53 is very unstable and it doesn't stain
13 well with antibodies.

14 So a p53 lesion can indicate an even earlier
15 tumor but it is not as strongly associated as a STIC.

16 Q. Are precursor lesions, STICs, and p53 signatures
17 associated with chronic inflammation?

18 A. Not as far as I'm aware, no.

19 Q. Why is that important?

20 A. Well, because, as I just said, if you want to
21 adduce a particular -- an agent as causing a
22 particular condition, you should be able to see that
23 that process or agent is present in the precursor
24 lesion because that's where the tumor is being formed.

25 Q. Have people actually looked at STICs under the

1 microscope to see if they are associated with chronic
2 inflammation?

3 A. Yes.

4 Q. Who has done that, which scientists?

5 A. A study by Malmberg looked at STICs from normal
6 patients and patients undergoing risk reduction
7 surgery for BRCA1 and BRCA2 lesions and found no
8 evidence of increased inflammation.

9 A second study by Dr. Shih, which is
10 unpublished but I reviewed, showed similar findings.

11 THE COURT: When was the other study done, by
12 Malberg, the earlier one you mentioned, when was that?

13 THE WITNESS: The date, I can look that up.
14 It is cited in my report. 2016.

15 MS. SHARKO: Malmberg is Exhibit A 91 to the
16 Tersigni certification, and it was published in 2016.

17 THE COURT: Thank you.

18 Q. Dr. Shih's paper is in the notebook of exhibits
19 and it starts in his expert report around page 25.

20 Who is Dr. Shih?

21 A. He is one of the world's prominent and respected
22 gynecological pathologists, and he is a professor at
23 Johns Hopkins Medical School.

24 Q. Would it be accurate to classify Dr. Shih's work
25 as a mere hypothesis?

1 A. No.

2 Q. Why not?

3 A. He actually posed a hypothesis as part of his
4 report and he tested that hypothesis by examining a
5 number of specimens, and that would be an experiment.
6 So it is not a hypothesis.

7 Q. Now, after you wrote and submitted your expert
8 report, did you have access to Dr. Shih's study?

9 A. Yes.

10 Q. Did you review it as critically as you would if
11 you were peer reviewing a paper for one of your
12 journals?

13 A. Yes.

14 Q. What conclusions did Dr. Shih reach regarding
15 STICs and chronic inflammation?

16 A. He found no evidence for an antecedent
17 inflammation in these lesions.

18 Q. What does all of this evidence tell us about
19 chronic inflammation and ovarian cancer pathogenesis?

20 A. It means that although several authors have
21 suggested chronic inflammation might play a role in
22 ovarian cancer, that remains a hypothesis and
23 basically speculation at this point.

24 Q. Switching topics.

25 Asbestos. Plaintiffs claim that the products

1 are contaminated with some amount of asbestos which we
2 deny. But if the defendants' talcum powder products
3 are shown to contain asbestos, would that matter to
4 your analysis, findings, and conclusions?

5 A. No.

6 Q. Why not?

7 MR. RESTAINO: Your Honor, I object. Dr. Neel
8 did not go into asbestos in his expert report. When
9 he was asked during his deposition about his opinions
10 regarding asbestos and ovarian cancer, he said, I have
11 no opinion in this regard, and we didn't go any
12 further into that based upon his opinions.

13 MS. SHARKO: It is not a problem because I
14 only have one final question in this area, and it is
15 exactly what he was asked and testified in his
16 deposition.

17 THE COURT: Let me hear the question.

18 Don't answer.

19 BY MS. SHARKO:

20 Q. I think the question was -- he said that it
21 wouldn't matter, and I asked, why not?

22 THE COURT: I guess the question is: Was that
23 asked in the deposition and explored?

24 MS. SHARKO: What I expect Dr. Neel is going
25 to say is exactly what he said at his deposition at

1 page 49:19 --

2 THE COURT: The issue was whether it was
3 explored in his deposition?

4 MS. SHARKO: Yes, it was.

5 THE COURT: Okay. Proceed.
6 Do you have the question?

7 THE WITNESS: Yes.

8 I was asked my understanding of my role in
9 this litigation, was to offer comments as to the
10 biological plausibility of talc products or talc in
11 ovarian cancer, and, therefore, I reviewed the
12 literature concerning that topic, and whatever was
13 used in that literature is what the plaintiffs are
14 alleging is the evidence in favor of biological
15 plausibility. So, no, it wouldn't matter what was in
16 them because I found no evidence supporting that
17 claim.

18 BY MS. SHARKO:

19 Q. Now, last big topic.

20 Dr. Saed, have you reviewed the expert report,
21 depositions, lab notebooks, peer reviews, drafts and
22 manuscripts of Dr. Saed?

23 A. Yes.

24 Q. Do you have an opinion to a reasonable degree of
25 medical and scientific probability on the methodology

1 that Dr. Saed used in coming to his opinions?

2 A. Yes.

3 Q. And what is your opinion?

4 A. It's seriously flawed on multiple levels.

5 Q. Does the data that Dr. Saed reports from his
6 experiment support the conclusion that exposure to
7 Johnson & Johnson's talcum powder products can cause
8 ovarian cancer?

9 A. No. And in my opinion they don't even address
10 that question.

11 Q. Now, your report, the reports of Dr. Boyd,
12 Dr. Shih, and Dr. Mossman, all critique Dr. Saed's
13 experiment at length, and the Judge has those. So I'm
14 going to cover a couple of the specific methodological
15 criticisms outlined in your report, but we're not
16 going to do everything.

17 What are SNPs?

18 A. SNPs are single nucleotide polymorphisms. So
19 SNPs are actually normal variants that are present in
20 all of us. If we compare my DNA to your DNA, or to
21 the Judge's DNA, we will have a variation on average
22 every 300 bases, and those variants are called SNPs.
23 Most SNPs have no biological consequence. They
24 represent the normal variation we have between all of
25 us in our courtroom.

1 SNPs are useful in science because they can be
2 used to map genes, and some SNPs are actually
3 deleterious and associated with disease.

4 Q. What do we know about these risk conferring
5 SNPs?

6 A. We know that large-scaled genetic association
7 studies called GWAS or genome-wide association
8 studies. So we know that large scale genetic
9 association studies or GWAS have mapped a number of
10 SNPs that are associated with risk of ovarian cancer.

11 Q. Where do I find this GWAS thing?

12 A. You can go to any browser and type in GWAS
13 catalog, and it will take you to the website; and when
14 you get to that website, you can put in any SNP or you
15 could put in any gene that has SNPs in it which all
16 genes do, or you can put in a disease like ovarian
17 cancer and it will list all the SNPs associated with
18 the disease to statistical significance.

19 Q. About how many SNPs are associated with an
20 increased risk of ovarian cancer?

21 A. The last time I did the analysis was around the
22 time of my deposition, and I went to GWAS catalog and
23 there are about 100 SNPs that have been associated to
24 varying degrees of statistical relevance with ovarian
25 cancer.

1 Another important point about SNPs is because
2 when you look at SNPs, the way these studies work,
3 they look at all of the SNPs at once. So there is a
4 statistical problem of multiple comparisons. So in
5 order to associate a given SNP with a disease, you
6 have to have a high statistical relevance. So only
7 ones that are statistically significant to a P value
8 of 10 to the minus 8 or less are statistically
9 significant. That's how you interpret the data on
10 GWAS.

11 Q. Doctor, did Dr. Saed study in his experiments
12 any of those SNPs that are associated with ovarian
13 cancer according to the GWAS compendium?

14 A. As far as I'm aware at the time I last checked
15 none of the SNPs that Dr. Saed studied in any of his
16 publications or for his deposition or expert report
17 have been linked conclusively to ovarian cancer
18 generation while many others have been.

19 Q. Now, do you have an opinion to a reasonable
20 degree of medical and scientific probability as to
21 whether talc can cause the specific changes in
22 specific SNPs that Dr. Saed believes it can?

23 A. Yes.

24 Q. And what is that opinion?

25 A. It is completely inconsonant with everything we

1 know about modern molecular biology.

2 Q. Why?

3 A. Well, I think it is easier to understand if I
4 explain how true mutagens work. A typical real
5 carcinogen or mutagen like benzopyrene or X-rays or UV
6 randomly introduce DNA damage into cells. So if you
7 have a plate of cells and you expose the cells to a
8 mutagen, there will be DNA damage, and some of that
9 DNA damage won't be repaired if you have enough
10 mutagen and you will get mutations, but those
11 mutations will be random. Then when you mutate a
12 gene, that provides a selective advantage to the cell
13 over time but not 48 or 72 hours, that clone of cells
14 will grow out, and you will see the mutation. But it
15 is impossible, as far as we know, for any substance to
16 quantitatively convert a particular locus to another
17 code within 48 to 72 hours, as Dr. Saed alleges, and
18 even more incredible to allege that multiple SNPs are
19 changed during that time period. It simply is not
20 credible.

21 Q. Can any substance do that that you are aware of?

22 A. Not that I'm aware of. In fact, even our most
23 modern engineering technologies like CRISPR /CAS
24 technology would not be able to do that. It would be
25 difficult to do with that technology.

1 Q. Let's go to animal studies. Is Dr. Saed's
2 experiment validated by animal studies?

3 A. No. As far as I know, he didn't do any animal
4 studies.

5 Q. Why is animal testing important when you go from
6 in vitro or the lab to in vivo or humans?

7 A. Well, the standard in the field to assess
8 whether a cell is a cancer cell is to see whether it
9 can form a tumor. There are examples of cells that
10 behave in a semi-transformed way in cellular assays
11 but do not form tumors, and they are not fully
12 developed cancer cells or can't be shown to be fully
13 developed cancer cells. So it is essential -- if you
14 are going to assert something is a cancer cell you
15 have to test it as its tumor-forming capability.

16 Q. What do the animal studies show with regard to
17 talc and ovarian cancer, limiting your answer to the
18 studies you discussed in your report.

19 A. There is no evidence there is any neoplastic or
20 preneoplastic changes caused by introduction of talc
21 either directly into the ovarian bursa or on the
22 perineum.

23 Q. Let's go now to lab notebooks. Did you review
24 Dr. Saed's lab notebooks?

25 A. I did.

1 Q. Why are lab notebooks created?

2 A. Because it is essential to create a
3 contemporaneous record of the hypothesis that's being
4 tested, the procedures that are being carried out to
5 test that hypothesis, the results that are obtained
6 and usually the provisional interpretation of those
7 results.

8 Q. Why is that important?

9 A. Because in order for science to be replicated.
10 You have to know what the experimentalist did.

11 Q. What did you tell your grad students about this?

12 A. Well, it's a little flippant. What I usually
13 tell them is that it is critical to keep good
14 laboratory notebooks because if they go outside and
15 get hit by a truck, after we're finished mourning
16 them, we want to be able to get on with their work.

17 Q. Now, what did your review of Dr. Saed's lab
18 notebooks and other materials tell you about his
19 laboratory practices?

20 A. They are irregular at best and sloppy at worst.

21 Q. Is it acceptable to use white-out in a lab
22 notebook?

23 A. No. I've never seen anyone use white-out in my
24 30 years as a faculty member.

25 Q. Dr. Neel, what does it mean to do an experiment

1 in triplicate?

2 A. This is complicated. In general science
3 requires replicates or replications, and there are two
4 different types of replicate -- biological replicates
5 and technical replicates. Biological replicates means
6 you take the same cells, you plate them on day one and
7 you expose them to some sort of a stimulus or agent;
8 and you read out a result, and you do the same thing
9 on days two and three.

10 Biological replicates are important to rule
11 out the typical biological variability that occurs
12 between cells.

13 Technical replicates means you do the same
14 assay in multiple times, and that has to do with the
15 precision of the assay measurement.

16 So, typically, experiments are done with both
17 biological and technical replicates.

18 Q. Let's go to cell lines. Did Dr. Saed test the
19 correct cell lines in his experiment in your opinion?

20 A. In almost all cases, no.

21 Q. For example, SKOV-3 what is the significance of
22 testing that to you?

23 A. I think the choice of SKOV-3, for example, is
24 inapt in two different ways. The first way is
25 Dr. Saed was investigating whether talc had effects on

1 the initiation or the causation of ovarian cancer.
2 SKOV-3 is already an ovarian cancer cell. So you
3 really can't learn much about whether something is
4 causing a cancer by testing something that is already
5 a cancer.

6 Secondly, SKOV-3 is not a high grade serous
7 ovarian cancer cell line. As I understand the
8 contention of the plaintiffs, there are major claims
9 on serous ovarian cancer.

10 Q. Let's go to oxidative stress and transformation.
11 Plaintiffs claim the papers by Buz'Zard and Shukla are
12 supportive of Dr. Saed's data and conclusions. Are
13 they consistent with Dr. Saed's data and conclusions?

14 A. No.

15 Q. Let's start with the Buz'Zard paper. What is
16 not consistent there?

17 A. If you actually look -- so one of Dr. Saed's
18 claims is that you could measure oxidative stress
19 simply by measuring the levels of the RNA or protein
20 for pro and/or antioxidant enzymes. I contend in my
21 report and testify now that it is essential to
22 actually measure reactive oxygen species in the same
23 cells.

24 In the Buz'Zard paper they used the same dose
25 of talc as Dr. Saed did and actually found ROS levels

1 were actually lower in the treated cells than in the
2 controlled cells, and Dr. Saed claims that ROS would
3 be higher. So I think that is definitely
4 inconsistent.

5 The second inconsistency is that the effects
6 of proliferation which Dr. Saed claims were also not
7 seen by Buz'Zard at the same dose of talc.

8 Q. What is gene expression?

9 A. As you know, we have multiple genes, and at any
10 given time, many of them are making RNA and that's
11 called gene expression. They are making messenger
12 RNA, and that's called gene expression. You can
13 measure that by doing today something called RNA
14 sequencing, or RNA-seq for short, and previously you
15 could do that by using Affymetrix arrays. That's what
16 gene expression is.

17 Q. Dr. Shukla's experiment as reported in her paper
18 found no changes in gene expression in cells exposed
19 to talc. Correct?

20 A. That's correct.

21 Q. Why is that significant?

22 A. Because if you don't significantly affect gene
23 express, that essentially means a substance is
24 biologically inert in that cell type.

25 Q. Plaintiffs and Dr. Saed claim talc is

1 pro-oxidative and that ovarian cancer is associated
2 with oxidative stress. What is oxidative stress?

3 A. Oxidative stress is when reactive levels of
4 reactive oxygen species exceed the level of
5 antioxidants in cells. So there is an excess of ROS.

6 Q. Dr. Neel, is it generally accepted in the
7 scientific and medical community that oxidative stress
8 causes ovarian cancer?

9 A. No. That's one of the hypotheses that exists,
10 but it is not in any way accepted.

11 Q. Is it generally accepted in the scientific and
12 medical community that oxidative stress plays a role
13 in the pathogenesis of ovarian cancer?

14 A. No.

15 Q. Do Dr. Saed's data even establish that talc
16 increases oxidative stress?

17 A. No.

18 Q. Do the data that Dr. Saed reports from his
19 experiment support the conclusion that inflammation or
20 oxidative stress are relevant to ovarian
21 carcinogenesis?

22 A. No. In fact, in my opinion, the experiments he
23 did can't even address that question.

24 Q. Let's go to CA-125, which Dr. Saed said was a
25 hallmark of ovarian cancer.

1 First of all, what is CA-125?

2 A. CA-125 is what we call a biomarker of ovarian
3 cancer. It's basically used by physicians to monitor
4 the level of ovarian cancer cells in a woman's body
5 who has ovarian cancer.

6 Q. Is it a hallmark of ovarian cancer?

7 A. Not insofar as hallmark means that it is
8 involved in the causation of the ovarian cancer.
9 There is no evidence to support that.

10 Q. Let's go to peer review. Did you review the
11 Gynecologic Oncology peer review comments on
12 Dr. Saed's manuscript?

13 A. Yes.

14 Q. What are your opinions as to those comments?

15 A. I agree with those criticisms.

16 Q. Are all peer review processes created equal?

17 A. No.

18 Q. What kind of peer reviews are given for an
19 abstract or a poster in your experience?

20 A. Having led many meetings, both national and
21 international, I'm very familiar with what happens
22 with poster reviews. What happens is the authors or
23 the applicants to the meeting submit an abstract.
24 That's all they submit. They don't submit any data.
25 They just submit the abstract. And then a decision is

1 made as to whether to give a poster presentation or a
2 talk.

3 The most interesting and most provocative
4 papers or abstracts, sorry, are given public oral
5 publications and the less interesting ones are given
6 posters.

7 Q. When it was asserted yesterday that 20 to 25
8 people peer reviewed Dr. Saed's paper before it was
9 published, what does that mean to you as a scientist
10 with over 200 peer reviewed publications and the
11 editor of six journals?

12 A. I think that's a highly misleading assertion.

13 Q. Okay. In summary, last topic, let's turn to the
14 relevance of what Dr. Saed did.

15 Do you have an opinion to a reasonable degree
16 of medical and scientific probability as to Dr. Saed's
17 study, including the conclusions that he draws, has
18 any relevance to the cause of human ovarian cancer?

19 A. Not in my opinion, no.

20 Q. Is it justifiable in your opinion from a
21 scientific point of view to extrapolate from
22 Dr. Saed's work to the cause of ovarian cancer in
23 humans?

24 A. No.

25 Q. Dr. Neel, are there good grounds for Dr. Saed's

1 opinions?

2 A. Not in my opinion, no.

3 Q. Do Dr. Saed's conclusions flow from facts known
4 to scientists or the methodology that Dr. Saed
5 employed?

6 A. No. As I've indicated, some of his conclusions
7 are completely inconsistent with modern molecular
8 biology.

9 Q. Does Dr. Saed's experiment tell us anything at
10 all about how talc behaves in the real world of the
11 female reproductive system?

12 A. No.

13 MS. SHARKO: Thank you very much.

14 Judge, I'm finished unless you have any
15 questions.

16 THE COURT: No. Thank you.

17 Plaintiffs want a few moments before you
18 start?

19 MS. O'DELL: Yes, please.

20 THE DEPUTY CLERK: All rise.

21 (Recess.)

22 (Continued on the next page.)

23 ///

24

25

1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **BENJAMIN G. NEEL**, resumed.

5

6 CROSS-EXAMINATION

7 BY MR. RESTAINO:

8 Q. Good morning, Dr. Neel. My name is John
9 Restaino. We had the brief privilege of meeting each
10 other during your deposition in New York. I have some
11 questions that I prepared and some questions based
12 upon your testimony this morning.

13 No. 1, first, it would be helpful for us to
14 establish the standard by which you wrote your expert
15 report and you based the opinions therein, because I
16 heard multiple times today your opinion was based on a
17 reasonable basis of scientific probability. Does that
18 sound familiar?

19 A. I don't recall exactly. I don't recall saying
20 that.

21 Q. Well, you were asked if your opinions were held
22 to a reasonable degree of medical certainty or medical
23 probability. Do you remember that?

24 A. Yes.

25 Q. That's not what you testified in your

1 deposition, did you, sir?

2 A. I probably testified to what I was asked.

3 Q. Let's look at what you testified as to the
4 standard you employed in developing your opinions and
5 writing your expert report.

6 For example, on the Bradford Hill viewpoints,
7 you are familiar with them?

8 A. Yes.

9 Q. You reviewed the Bradford Hill viewpoints in
10 preparation for writing your expert report. Right?

11 A. Yes.

12 Q. It was reference 5 in your expert report. And
13 you were asked at your deposition on page 153, 23 --

14 A. I don't have that deposition. Do I? Do I have
15 it?

16 THE COURT: Is it in the binder you gave to
17 me?

18 MR. RESTAINO: Page 153, 23, to page 154, 1.

19 MS. SHARKO: I object. I don't see how this
20 goes to the questions he was asked.

21 THE COURT: I think we're looking at different
22 things. You are asking him generally what is the
23 standard, and we know what the standard is under
24 Daubert and how opinions should be held. Now, you are
25 asking specifically about Bradford Hill. I think it's

1 a bit of a disconnect, but feel free to ask him about
2 Bradford Hill.

3 BY MR. RESTAINO:

4 Q. In fact, throughout your deposition it was your
5 opinion the evidence must be compelling. Correct?

6 A. Yes.

7 Q. Definitive?

8 A. Well, I think it probably would depend on the
9 context of the exact question when I said
10 "definitive."

11 THE COURT: There is a difference between his
12 opinions, and we're looking at something different
13 here. Keep going.

14 Q. In order to have an argument in favor of
15 biological plausibility, do you have an opinion
16 whether or not the evidence must be compelling and
17 definitive?

18 A. I understand where the concern is. The evidence
19 itself has to be compelling and definitive, but it
20 doesn't mean the evidence covers everything. The
21 evidence produced has to be compelling and definitive.
22 Is that helpful?

23 Q. Doctor, you are a cancer biologist. Correct?

24 A. Yes.

25 Q. An MD and Ph.D.?

1 A. Yes.

2 Q. When is the last time you actually examined a
3 patient?

4 A. 1988.

5 Q. Would that be the last time you examined the
6 genitals of a female?

7 A. Yes.

8 Q. You are not an oncologist actively treating
9 patients with cancer. Correct?

10 A. Correct.

11 Q. Doctor, you are a cancer biologist that works in
12 a laboratory. Correct?

13 A. I work in a laboratory for part of my time, and
14 the rest of my time I run the Perlmutter Cancer Center
15 at NYU Langone, and in that capacity I'm responsible
16 for the entire cancer service line and all cancer
17 research at NYU Langone Health.

18 Q. That's more of a role as an administrator.
19 Correct?

20 A. Yes.

21 Q. But in the laboratory you conduct research
22 involving cancer biology?

23 A. I oversee the research. I don't do many
24 experiments anymore. My post docs would think that is
25 a bad thing.

1 Q. Have you or the individuals you oversee ever
2 conducted a study looking at the molecular effects of
3 talc?

4 A. No.

5 Q. Now, in preparing your opinions for this case
6 and your expert report, it is true one of the
7 methodologies you employed was an online search using
8 search engines such as Google and PubMed?

9 A. Yes.

10 Q. And you developed keywords to conduct that
11 search . Correct?

12 A. Yes.

13 Q. Two of the key words you utilized were
14 "ovarian" and "cancer." Correct?

15 A. Yes.

16 Q. And another one was "inflammation." Correct?

17 A. Yes.

18 Q. On PubMed, if one types in "ovarian cancer,"
19 then a list of a lot of articles are going to come up
20 that either have "ovarian cancer" in their title or
21 "ovarian cancer" in the corpus of the article.

22 Correct?

23 A. Yes. I didn't just do "ovarian cancer." I did
24 "ovarian cancer" and various questions because,
25 obviously, "ovarian cancer" would be very large, just

1 to clarify.

2 Q. And you also searched for "inflammation"?

3 A. In the context of "ovarian cancer." So it would
4 be "ovarian cancer" and "inflammation." It's been a
5 long time, so I don't remember exactly everything I
6 searched, to be honest.

7 Q. Once the list of articles came up on the screen
8 in PubMed -- last night, when I ran a search using
9 "ovarian cancer," "talc" and "inflammation," there
10 were 1,122 articles that came up. Then you scanned
11 those articles that were germane to your opinions.
12 Correct?

13 A. Yes.

14 Q. Some you selected and some you did not select.
15 Correct?

16 A. Yes. I looked at the abstracts for most of
17 them, as I recall.

18 Q. And from those abstracts you then selected
19 articles that you would review in full. Right?

20 A. Correct. Mostly focused on the more recent
21 data.

22 Q. Now, once you saw the abstracts -- looking at
23 "talc" and "inflammation," there are articles written
24 and published that come down on the side of talc
25 causing inflammation and talc not causing

1 inflammation. Is that correct?

2 A. Yes.

3 Can I expound on that? Some people would
4 consider granulomas to be inflammation. So there is
5 no that question talc causes granulomas. The issue I
6 was looking for when I prepared my expert report was
7 whether talc caused the kind of inflammation that is
8 associated with cancer or cancer initiation. That was
9 the focus of my expert report.

10 Q. Granuloma formation is one of the results of the
11 body's immune system reacting to, for example, a
12 foreign body. Correct?

13 A. That's correct.

14 Q. That is an inflammatory reaction?

15 A. Again, to clarify, granulomas are not associated
16 with ovarian cancer development. Inflammation is a
17 broad term, as you know, and it is important to focus
18 on the key aspects when you are trying to investigate
19 a subject.

20 Q. However, for clarification, inflammation would
21 be the first step in acute foreign body reaction
22 inflammation which then can in some cases go on to
23 cause chronic inflammation, which has been caused with
24 cancer formation or the body may form a granuloma to
25 wall that foreign body or splinter one might get

1 walking on the boardwalk?

2 A. I think it is much more complicated than you are
3 making it.

4 Q. There are specific cells we have within our body
5 that are part of the innate immune system. Correct?

6 A. That's correct.

7 Q. These would include macrophages?

8 A. Correct.

9 Q. Lymphocytes?

10 A. Lymphocytes are part of the adaptive immune
11 system and not the innate immune system.

12 Q. Can you explain that?

13 A. Macrophages are part of the innate immune
14 system. These are the official cells that respond to
15 invaders like infections, and then they trigger the
16 production of cytokines and chemokines which can lead
17 to the engagement of the innate immune system.

18 Lymphocytes are part of the innate immune system.

19 Q. What other cells in addition to the lymphocytes
20 would you expect to find within the innate system?

21 A. As I just said, lymphocytes are not part of the
22 innate system.

23 Q. I'm sorry. The adaptive.

24 THE COURT: I want to be clear. Lymphocytes
25 are part of --

1 A. (Continuing) -- lymphocytes are the sine qua non
2 of the adaptive immune system. Innate and adaptive.
3 Lymphocytes -- there are two major classes of
4 lymphocytes. T lymphocytes and B lymphocytes. T
5 lymphocytes mediate cell immunity and B lymphocytes
6 produce antibodies. They are the adaptive immune
7 system.

8 Q. Are there other cells that are listed or can
9 overlap with the adaptive system?

10 A. If you are taking about NK cells, most people
11 would classify them as innate. They are sort of an
12 overlap category. It stands for natural killer cells.

13 Q. The presence of NK cells can suggest chronic
14 inflammation. Correct?

15 A. Yes.

16 Q. The presence of lymphocytes can indicate chronic
17 inflammation?

18 A. Yes.

19 Q. The presence of macrophages can indicate chronic
20 inflammation?

21 A. Yes.

22 Q. Doctor, according to your expert report, you
23 published 234 peer-reviewed manuscripts. I'm assuming
24 since the time you filled this out, there are probably
25 more?

1 A. I think this was pretty up to date. There may
2 be one more.

3 Q. You also published 33 invited review articles.
4 Correct?

5 A. Correct.

6 Q. We heard yesterday from Dr. Saed that an invited
7 review article involves an individual who is
8 recognized by a journal, by a journal editor, whatever
9 the case may be, to be an expert in that area and
10 asked to write a review of the literature germane to
11 that particular topic of which the person is an
12 expert. Right?

13 A. It is a little bit more complicated than that.
14 I guess I would have to say no because it is a little
15 more complicated than that.

16 Q. Are you aware of any situation where a review
17 article has been written by someone who was not an
18 expert in that field?

19 A. Yes.

20 Q. Have you ever written a review article on an
21 area in which you do not hold expertise?

22 A. I try not to.

23 Q. So you have not?

24 A. No.

25 Q. Have you ever written a review article looking

1 at the inflammatory effects of talcum powder?

2 A. No, I haven't.

3 Q. Have you ever written a review article looking
4 at the inflammatory aspects of involving premalignant
5 ovarian cancer?

6 A. No.

7 Q. In your review of the abstracts and then
8 articles that you have selected to review for your
9 opinions, did you see abstracts and articles that were
10 contrary to your opinions?

11 A. On the surface, yes.

12 Q. Did you read those in addition to those that
13 supported your opinions?

14 A. Of course.

15 Q. How did you go about weighing which article
16 would be utilized in your expert report? For example,
17 the con and the pro, what was the methodology you used
18 to weigh those?

19 A. The same methodology I would use to write any
20 review article for the scientific literature. If I
21 thought the topic was on point, then I would
22 definitely include. If I thought the topic was not, I
23 wouldn't include it.

24 Q. If the topic was on point and the conclusion was
25 long-term genital exposure to talc resulted in an

1 increased risk of ovarian cancer, would you include
2 that?

3 A. Yes.

4 Q. You testified of your 234 peer-reviewed
5 manuscripts you have been cited 45,000 times.
6 Correct?

7 A. That was at the time of submission of my CV,
8 yes. It may be a little higher now.

9 Q. Why did you share that information with the
10 Court?

11 A. I think it speaks to the level of impact that I
12 have in the field and my expertise along with my H
13 index.

14 THE COURT: What is that?

15 THE WITNESS: The H index is the number of
16 papers you have that have been cited that number of
17 times. So 107 papers cited at least 107 times.

18 Q. You consider the H index to be indicative of
19 general acceptance of your work?

20 A. I think all metrics are imperfect, but the H
21 index is thought to be along with the i10 and several
22 other metrics you can use them together to sort of
23 assess expertise, yes.

24 Q. A reader seeing your work and noticing an H
25 index of what is probably 107 would then consider your

1 work to be at least worthy of reading. Would you not
2 agree?

3 A. Yes, in general.

4 Can I clarify?

5 Q. Of course.

6 A. Generally, readers of papers don't necessarily
7 look at H indices to evaluate that. People in the
8 field know the names of people in the field.

9 Q. Your time at Harvard, do you know Dr. Graham
10 Colditz? He is a physician epidemiologist?

11 A. I believe he is at Washington University,
12 St. Louis.

13 Q. Are you familiar with Dr. Graham Colditz's work
14 looking at talc and ovarian cancer?

15 A. He is an epidemiologist. So if he was involved
16 in the epidemiological study I read, then, yes. I
17 don't remember all the authors on the papers, frankly.

18 Q. Did you read an expert report written by
19 Dr. Graham Colditz in talc litigation?

20 A. I did not.

21 Q. Do you know that Doctor Graham Colditz has
22 concluded long-term genital to talc has resulted in an
23 increased risk of ovarian cancer?

24 MS. SHARKO: I object. Dr. Colditz is not an
25 expert in this particular case. No expert report was

1 served by him.

2 THE COURT: Mr. Restaino.

3 BY MR. RESTAINO:

4 Q. When you were doing your PubMed search for
5 ovarian cancer, did you see the publications by
6 Dr. Graham Colditz?

7 A. As I just indicated, Mr. Restaino, I reviewed a
8 large number of epidemiological studies and I don't
9 recall who was the author on all of those studies. I
10 remember some of the names but not all of them, but I
11 do remember a large number of epidemiological studies.
12 I don't remember the authors, all of the authors on
13 each of those studies and the most recent
14 meta-analyses.

15 Q. In looking at the various epidemiological
16 studies that you did review, did you pull those
17 studies that found an association in addition to those
18 that did not?

19 A. Yes.

20 Q. Do you know what Dr. Graham Colditz's H index
21 is?

22 A. I'm sure it is quite high.

23 Q. If I represent to you Dr. Colditz is the No. 2
24 cited author in the world with an H index of 287,
25 would that surprise you?

1 A. No.

2 MS. SHARKO: Objection. Relevance.

3 THE COURT: He's answered it.

4 Move on.

5 BY MR. RESTAINO:

6 Q. Doctor, you were asked about ROS reactive oxygen
7 species?

8 A. Yes.

9 Q. Anything that leads to increased inflammation
10 can lead to an increased production of reactive oxygen
11 species. Correct?

12 A. There are two conditionals there. Can you
13 simplify that question.

14 Q. Let me reask the question.

15 It is true anything that leads to increased
16 inflammation can result in increased production of
17 ROS?

18 A. If the answer is, is it possible? Yes.

19 Q. Is it more likely than not?

20 A. That anything that causes chronic inflammation
21 -- anything that causes chronic inflammation where
22 there is macrophages and neutrophils in the
23 environment, if they are chronically stimulated, they
24 can produce excess reactive oxygen species, yes, not
25 lymphocytes.

1 Q. You just mentioned a cell type that hadn't been
2 mentioned previously, and that's neutrophils.

3 A. I mentioned that earlier.

4 Q. Are neutrophils part of the adaptive or innate
5 system?

6 A. Innate. Innate is classically defined as
7 macrophages and neutrophils.

8 Q. When there is an inflammatory process, there is
9 not, for lack of a better word, barrier that prevents
10 the macrophages, neutrophils from co-mingling with
11 lymphocytes. Correct?

12 A. Sometimes. It depends on the type of
13 inflammation, what is in the inflammatory
14 microenvironment.

15 Q. Do you agree that reactive oxygen species have
16 the potential to damage DNA and lead to mutations
17 under certain conditions?

18 A. Yes.

19 Q. In fact, if we can bring up on the slide your
20 expert report, page 8, in the first full paragraph.
21 You wrote agents or conditions that lead to increased
22 inflammation can result in the production of reactive
23 oxygen species ROS which can damage DNA and lead to
24 mutations under the certain conditions?

25 That's your opinion. Correct?

1 A. Yes.

2 Q. You will agree any agent that promotes
3 especially chronic inflammation can result in increase
4 ROS formation?

5 A. It is possible.

6 Q. Is it more likely than not that it is going to
7 occur?

8 A. It depends on the type of inflammation.

9 Q. And that increased ROS development can result in
10 mutagenesis?

11 A. Yes. And that can be tested for.

12 Q. Now, associated with reactive oxygen species is
13 also oxidative stress. Correct?

14 A. That's not exactly correct.

15 Q. Isn't oxidative stress produced by an imbalance
16 between ROS production and the body's ability to
17 detoxify those?

18 A. That's an accurate statement.

19 Q. Would you agree that oxidative stress is
20 generally accepted as a critical path though
21 physiological mechanism in different human pathologies
22 including cancer?

23 A. Can you repeat the question.

24 Q. It is generally accepted that oxidative stress
25 is a critical pathophysiological mechanism in

1 different frequent human pathologies which can include
2 cancer?

3 A. Yes. But not all. Just so I'm clear on the
4 question, because it had a lot of modifiers.

5 Q. ROS can cause protein damage?

6 A. Yes.

7 Q. ROS can cause lipid damage?

8 A. Excess ROS.

9 Q. Thank you for saying that because you testified
10 that this is also a normal process?

11 A. Yes. ROS production is a normal process, yes.

12 Q. And apoptosis is a normal physiological process?

13 A. Absolutely.

14 Q. We are all experiencing apoptosis now by virtue
15 of being alive. Right?

16 A. Yes.

17 Q. It's the programmed normal death of a cell?

18 A. Yes.

19 Q. Cellular proliferation is a normal cellular
20 process?

21 A. In some cells, yes.

22 Q. All of us in the courtroom are undergoing in
23 some of our cells cellular proliferation right now.
24 Right?

25 A. Yes.

1 Q. Excess abnormal apoptosis is not normal
2 physiological process. Correct?

3 A. That's correct.

4 Q. Excess cellular proliferation is not normal.
5 Correct?

6 A. Correct.

7 Q. We all need oxygen here in this room to stay
8 alive. Correct?

9 A. Yes.

10 Q. If this room was filled with 100 percent oxygen,
11 we are not going to stay alive very long?

12 A. That's complicated. What do you mean by "very
13 long."

14 THE COURT: I think we can move on.

15 Q. There is a difference between normal
16 physiological responses and abnormal physiological
17 responses even if they are the same thing, for
18 example, as cellular proliferation?

19 A. Yes.

20 Q. Now, you agree that different lifestyle and
21 environmental related factors may be pro-carcinogenic?

22 A. Yes.

23 Q. All cancer does not develop strictly because of
24 genetic abnormalities?

25 A. That's incorrect. All cancers result from

1 genetic abnormalities. That's what cancer is.

2 Q. Is it also true those genetic mutations or
3 abnormalities could be secondary to environmental
4 factors?

5 A. Yes.

6 Q. So in that sense, almost all cancers are not
7 only genetic but only environmental in basis?

8 A. That's incorrect.

9 Q. Are you aware of individuals who published to
10 the contrary?

11 A. I'm not sure. I would have to see the actual
12 papers that you are referring to because that's your
13 interpretation. I'm not sure that I would agree with
14 your characterization of the papers.

15 Q. Do you agree that cigarette smoking is linked to
16 the development of lung cancer?

17 A. Yes.

18 Q. Do you agree that excessive UV light is
19 associated with the development of cancer,
20 specifically especially malignant melanomas?

21 A. Skin cancer in general, yes.

22 Q. In fact, you have said people who use tanning
23 beds have over a 50 percent increased risk of
24 developing melanomas. Correct?

25 A. Yes.

1 Q. That's as a result of the UV light?

2 A. That's correct.

3 Q. The UV light is an environmental factor. Right?

4 A. Absolutely.

5 Q. Not everyone who sits long-term in tanning beds
6 develop cancer?

7 A. That's correct.

8 Q. In fact, only 10% of long-term smokers, those
9 with high pack year histories, develop lung cancer?

10 A. I believe I put that in my report.

11 Q. You did. That would indicate there is a genetic
12 component also. Correct?

13 A. Not exactly correct. Can I elaborate?

14 Again, this is one of the areas that's very
15 confusing to the lay public. All cancer is genetic in
16 the sense that it derives from changes in genes or
17 their gene expression. By that criteria, that's how
18 scientists talk about cancer. There is not a single
19 credible scientist who would say that cancer is not a
20 genetic or genomic disease. What you are, I believe,
21 referring to are inherited genomic predispositions, or
22 something like that. That's different than saying
23 cancer is not genetic. All cancer is genetic.

24 Q. There is a difference between inherited
25 mutations and somatic?

1 A. Yes.

2 Q. Can you explain to the Court what is meant by a
3 somatic?

4 A. A somatic mutation is one that occurs after
5 birth.

6 Q. On page 68 of my outline, looking at your expert
7 report, Doctor, it is your opinion most cancer causing
8 somatic mutations probably occur as a consequence of
9 unrepaired errors in DNA replication and are thus mere
10 bad luck. Put another way, the cancer causing
11 environment is our own body and the enemy lies within.
12 That's your opinion. Correct, sir

13 A. I wrote it in my report, yes.

14 Q. You have four references after that?

15 A. Yes.

16 Q. All four references by Tomasetti and Vogelstein?

17 A. Yes.

18 Q. Now, as you mentioned a moment ago, first of
19 all, it is your opinion 60 percent of cancers are
20 preventable. Correct?

21 A. Yes.

22 Q. Not just bad luck?

23 A. Well, the environment, your body is still
24 causing the cancers, yes.

25 Q. Now, the publications by Tomasetti and

1 Vogelstein, that resulted in a impressive controversy
2 in the medical literature, did it not?

3 A. Yes.

4 Q. But you provide four articles by just Tomasetti
5 and Vogelstein?

6 A. Yes.

7 Q. Now, can you go to Exhibit PSC Neel 21. There
8 is a paper by Tomasetti and Vogelstein titled,
9 "Variation in Cancer Risk Among Tissues Can Be
10 Explained by the Number of Stem Cell Divisions."

11 A. Yes.

12 Q. This is part of the literature search you did in
13 finding these articles, sir?

14 A. Yes.

15 Q. And you are utilizing these articles as giving a
16 fair and balanced approach to what your opinions are
17 in this litigation?

18 A. I don't remember if I cited this particular
19 paper. I would have to see.

20 Q. I believe this is your reference No. 14.

21 A. Okay.

22 Q. Now, amongst the responses when this paper was
23 published -- first of all, if you look four lines up
24 from the time they say, "The majority is due to bad
25 luck, that is, random mutations arising during DNA

1 replication in normal noncancerous stem cells."

2 Correct?

3 A. Yes.

4 Q. You put that in your expert report?

5 A. Yes. Not exactly the same statement.

6 Q. Now, if we could go to Exhibit PSC Neel 12,
7 there is a paper by Nowak and Waclaw, titled, "Genes
8 Environment and Bad Luck," explain cancer risk in a
9 statistical sense. This was published in Science in
10 March 2017, and Science is a highly rated scientific
11 journal. Correct, sir?

12 A. Yes.

13 Q. You are not a statistician. Correct?

14 A. No.

15 Q. Now, in the first paragraph of this paper they
16 write:

17 "It is a human trait to search for
18 explanations for catastrophic events and rule out mere
19 chance or bad luck. When it comes to human cancer,
20 the issue of natural causes versus bad luck was raised
21 by Tomasetti and Vogelstein about two years ago.
22 Their study, which was widely misinterpreted as saying
23 that most cancers are due neither to genetic or
24 inheritance nor environmental factors but simply bad
25 luck, sparked controversy. To date, a few hundred

1 papers have been written in response including two to
2 six with some such as two coming to opposite
3 conclusions."

4 Do you agree the Tomasetti/Vogelstein paper
5 sparked controversy?

6 A. Yes. I'm not claiming all cancers are caused by
7 bad luck. I'm saying definitely -- multiple things
8 contribute to any given cancer. Inherited
9 predisposition can contribute. Abnormal replication
10 errors that just occur by bad luck, and in some cases
11 environmental agents.

12 Q. In your expert report, which Her Honor read and
13 has to read, you wrote specifically: "Rather most
14 cancer causing somatic mutations" -- somatic being
15 after birth -- "probably occurs as a consequence of
16 unrepaired errors in DNA replication and are thus mere
17 bad luck"?

18 A. I think the context is that not all cancers are
19 caused by environmental agents; and if I miswrote or
20 misspoke, I'm happy to clarify.

21 Q. It's not your opinion as an expert in cancer
22 biology that women who have developed ovarian cancer
23 perhaps due to long-term genital use of talc didn't
24 get the cancer from the talc but it is just bad luck
25 on their part. That's not their testimony, is it?

1 A. That's a very difficult question. It is my
2 testimony that there is no evidence perineal
3 application of talc contributes to ovarian cancer in
4 any woman. That is my testimony. That's more clear.

5 Q. Looking at those studies that have a contrary
6 opinion the epidemiological studies that come to a
7 contrary opinion, it is not your opinion that talc had
8 no role at all because this is all due to merely bad
9 luck?

10 A. That's a mischaracterization of my opinion.

11 Q. If so, I apologize, and I just want that
12 clarified.

13 A. Would you like me to clarify my opinion? That
14 is a mischaracterization of my opinion.

15 THE COURT: Tell me what your opinion is.

16 THE WITNESS: My opinion is there is no
17 evidence from the epidemiological studies alone that
18 makes it more likely than not that perineal talc
19 causes ovarian cancer. That's my opinion.

20 BY MR. RESTAINO:

21 Q. Have you seen the epidemiological studies that
22 have found an increased risk between long-term
23 exposure to talc and ovarian cancer?

24 A. Yes, I have.

25 Q. That is evidence in and of itself. Correct?

1 A. No. That is evidence of an association between
2 a particular agent and a particular outcome. There
3 are also many other studies that show the opposite
4 including the more compelling studies.

5 Q. Compelling in your opinion?

6 A. Compelling as I understand it from all
7 epidemiologists that cohort studies are more reliable
8 than case-control studies. As I said, I'm not an
9 epidemiologist.

10 Q. Would you agree a properly designed, properly
11 performed case-control study outweighs a poorly
12 designed, poorly conducted cohort study?

13 A. I don't have an opinion on that.

14 Q. You agree smoking causes cancer?

15 A. Smoking causes several kinds of cancer, yes.

16 Q. You would agree asbestos causes lung cancer?

17 A. Yes.

18 Q. Do you know if there is an actual increased risk
19 in individuals who both smoke and are exposed to
20 asbestos?

21 A. Yes.

22 Q. That would be known as the -- could be described
23 as dramatically cocarcinogenic. Does that sound
24 familiar?

25 A. Yes. I think I wrote that.

1 Q. Are you familiar with the epidemiological term
2 "interaction or effect modification"?

3 A. I'm not an expert in epidemiology. I've read
4 that. I can't state with confidence what that means.

5 Q. How about if we just go along with "dramatically
6 cocarcinogenic," inasmuch as you wrote that?

7 A. I understand what that means.

8 Q. There are risk factors associated with the
9 development of ovarian cancer. Correct?

10 A. Yes.

11 Q. If we can turn to your expert report, page 12.
12 In the bottom paragraph you have a section that you
13 wrote, expert report.

14 Sir, you wrote:

15 "Multiple factors rather than a single cause
16 likely contribute to ovarian cancer generation. It is
17 difficult to attribute a specific case of cancer to a
18 single cause."

19 You wrote that, sir. Correct?

20 A. Yes.

21 Q. In fact, it is true that most disease states are
22 multifactorial with the exception of trauma or direct
23 poisoning. Don't you agree?

24 A. I think that's generally true, yes.

25 Q. Most causes are multifactorial. Would you

1 agree?

2 A. I don't know what you mean.

3 Q. In order to determine something is actually
4 caused in effect most of the time, that's
5 multifactorial?

6 A. I'm not sure I thought that through enough to
7 give a yes or no answer.

8 Q. If we go to page 13 of your expert report, you
9 are discussing risk factors, you write:

10 "There are several clearly established risk
11 factors for all ovarian cancer and others for specific
12 types" reviewed in 43.

13 A. Yes. Can I clarify?

14 Q. Of course.

15 A. (Continued reading.)

16 For example, those risk factors were
17 attributed to all ovarian cancers. It doesn't mean
18 that the studies actually broke out their attribution
19 to specific subtypes, and I think I was a little loose
20 in the way I wrote that sentence.

21 Q. Take a look at that. Your reference is
22 reference 43, "Reid, et al, Epidemiology of Ovarian
23 Cancer, a Review."

24 Sound familiar, sir?

25 A. Yes.

1 Q. Now --

2 A. That's by Tom Sellers, the senior author on that
3 paper.

4 Q. If you go --

5 A. Can you tell me what exhibit that is?

6 Q. PSC Neel 16.

7 A. What page?

8 Q. Page 11. There is a section there titled
9 "Genetic Epidemiology."

10 See that?

11 A. Yes.

12 Q. Reference 43, they write:

13 "One of the most significant risk factors for
14 ovarian cancer is a family history of the disease.
15 First degree relatives of probands have a 3 to 7 fold
16 of increased risk especially if multiple relatives are
17 affected and at an early age of onset."

18 Did I read that correctly?

19 A. Yes.

20 Q. A proband is the starting point in a family for
21 a genetic study?

22 A. It is the person in this case who has the
23 cancer. Probably, that's what they meant.

24 Q. Doctor, you would agree it is biologically
25 plausible for a family history of ovarian cancer to be

1 a risk factor for the development of ovarian cancer?

2 A. This is one of those cases where I feel I wasn't
3 exactly accurate. Some of the genetic predispositions
4 that Dr. Sellers cites in his paper are only risk
5 factors for one subtype of ovarian cancer. For
6 example, BRCA1, BRCA2, those DNA repair mutations are
7 all high grade serous cancer risk factors.

8 However, this paper by Reid does not break
9 down the description of ovarian cancer and risk
10 factors to subtypes, does it?

11 A. At this time, actually does, if you read the
12 paper.

13 Q. Let's go through the different risk factors and
14 their references. Reid provides four references for
15 the statement, "The risk of ovarian cancer and first
16 introduce degree relatives are probands, 43 to 47."

17 A. Okay.

18 Q. Did you pull those references numbers 43 and 47
19 to review them?

20 A. I would have to go see 43 and 47.

21 No, I didn't read those papers. It's well
22 known those genes cause high grade serous ovarian
23 cancer. The mutations in those genes are risk factors
24 for high grade serous cancers.

25 Q. The four references that Sellers -- that they

1 referenced, these are four epidemiological studies
2 published in the peer-reviewed literature. Correct?

3 A. I didn't read them. I assume they are
4 epidemiological studies.

5 Q. Because you are relying on what Dr. Reid wrote
6 as your reference?

7 A. I'm relying on the fact BRCA1 and BRCA2 and
8 these genetic factors are associated with high grade
9 serous ovarian cancer. That is well-established
10 knowledge for anybody who works in the field of
11 ovarian cancer.

12 Q. You referenced Reid for your statement there are
13 several clearly established risk factors for all
14 ovarian cancers. Right?

15 A. I did write that. I meant that some papers will
16 say ovarian cancer and not break it down; especially
17 the earlier papers which were published before these
18 subtypes were appreciated.

19 Q. In the same exhibit, if we go to page 11, on the
20 right column there is a heading risk factors and
21 preventive factors, hormonal and reproductive risk
22 factors. See that?

23 A. Yes.

24 Q. They write there:

25 "Epidemiological research has clearly

1 implicated hormonal and reproductive factors in the
2 pathogenesis of ovarian cancer."

3 Do you agree epidemiological research has
4 clearly implicated hormonal and reproductive factors
5 in the pathogenesis of ovarian cancer?

6 A. Yes. But with qualifications that, for example,
7 the risk for hormonal factors appear to be more for
8 the Type I endometrioid tumors, for example.

9 Q. Is it biologically plausible for a woman without
10 a history of giving birth to have higher risk factors
11 for the development of ovarian cancer?

12 A. Yes, it is biologically plausible.

13 Q. They next describe age at menarche and age at
14 menopause. They write:

15 "According to incessant ovulation hypothesis,
16 early age at menarche and late age at menopause
17 increases risk by increasing the number of ovulatory
18 cycles."

19 Did I read that correctly?

20 A. Yes.

21 Q. Do you agree that the incessant ovulation
22 hypothesis, at an early age of menarche and menopause
23 at a later age increase the risk of ovarian cancer?

24 A. With the qualification Dr. Sellers also makes on
25 page 13 at the end of the paragraph, regardless the

1 available --

2 THE COURT: Slow down a little bit.

3 A. Sorry. On page 13 Dr. Sellers also writes:

4 "Regardless, available evidence suggests the
5 magnitude of any effect is small."

6 With that qualification, which Dr. Sellers has
7 also made in his review,.

8 Q. "Small" still means there is an increased risk?

9 A. There is an increased risk, yes.

10 Q. And it is an huge increased risk for the woman
11 who develops ovarian cancer?

12 A. That's hard to answer. You can't make a risk
13 assessment for an individual.

14 THE COURT: He didn't expect an answer to
15 that. It is more of a statement.

16 THE WITNESS: I'm trying to help.

17 Q. Dr. Reid also provided references for the notion
18 that the increased risk of ovarian cancer associated
19 with the age of menarche and menopause. Did you pull
20 those studies and review them.

21 A. I probably looked at some of them but not all of
22 them. Again, the purpose of my report was to assess
23 the biological experiments. I read the
24 epidemiological experiments to see if there was any
25 evidence at all in favor of the hypothesis.

1 Q. Doctor, parity indicates a number of pregnancies
2 reaching viable gestational age, including live births
3 and still births. Correct?

4 A. Yes.

5 Q. They have a section on page 13 they titled
6 "Parity and Infertility." See that?

7 A. Yes.

8 Q. They write:

9 "The association between pregnancy and ovarian
10 cancer risk has been studied extensively."

11 See that, sir?

12 A. I do.

13 Q. Do you agree that association has been studied
14 extensively?

15 A. I think Dr. Sellers would be more able to make
16 that statement than I, but yes, I agree.

17 Q. Further down they write:

18 "Indeed, parous women have a 30 percent to 60
19 percent lower risk than nulliparous women" and they
20 have many references, "and each additional full-term
21 pregnancy lowers risk by approximately 15 percent.

22 Did you pull all those references?

23 A. I did not pull all of those studies, no.

24 Q. Do you know if any of those referenced
25 epidemiological studies break down the analysis by

1 ovarian cancer subtype?

2 A. I don't know if those studies do that, but a
3 more recent study does.

4 Q. Is that more recent study published in your
5 expert report?

6 A. It is in my supplemental report. It is not in
7 my original report.

8 Q. Now, continuing on, on page 13 they have a
9 section on lactation. Do you see that, sir?

10 A. Yes.

11 Q. Once again they write:

12 "Both the incessant ovulation and gonadotropin
13 hypotheses would predict lactation reduces the risk of
14 ovarian cancer. In fact, most studies indicate a
15 slight protective affect from breast feeding with odds
16 ratio approximating 0.6, to 0.7" with many references
17 "although some have not,." And other references.

18 Correct?

19 A. Yes.

20 Q. Did you pull those epidemiological studies?

21 A. No.

22 Q. Do you know if any of those studies in this
23 paper by Reid et al, which is your reference 43 and
24 you are relying upon break down the ovarian cancer by
25 subtype?

1 A. I don't.

2 Q. If we go over to page 14, right column, final
3 paragraph:

4 "Several gynecologic procedures appear to
5 influence the risk for ovarian cancer. It is well
6 established that among high risk women bilateral
7 prophylactic oophorectomy decreases risk by at least
8 90 percent reference 176."

9 Do you agree with Reid at all that several
10 gynecologic procedures appear to influence the risk of
11 ovarian cancer?

12 A. Yes.

13 Q. Do you agree it is well-established among high
14 risk women bilateral prophylactic oophorectomy
15 decreases that risk by at least 90 percent?

16 A. Yes.

17 Q. Did you pull that reference?

18 A. I don't recall if I pulled that reference.
19 That's well-established.

20 Q. And that looks at ovarian cancer in general, not
21 by subtype. Correct?

22 A. Yes.

23 Q. Now, Doctor, is it biologically plausible for a
24 woman who has undergone a tubal ligation -- for a
25 woman who has not undergone tubal ligation to be a

1 risk factor for ovarian cancer -- how about if I
2 strike that and try that in English.

3 Is it biologically plausible for a woman who
4 has not undergone a tubal ligation to have a higher
5 risk for the development of ovarian cancer?

6 A. Actually, if you read the complete context of
7 Dr. Sellers' review, you will notice in the last
8 sentence of that section, says:

9 "Indeed, this hypothesis is supported by
10 epidemiological studies that show the strongest
11 associations between tubal ligation and ENOC carcinoma
12 and CCOC" -- which stands for clear cell carcinoma.

13 A. Again, there is biological plausibility for that
14 because it blocks the egress of endometriotic lesions
15 from the uterus to the tube. I think that's a good
16 example of how modern epidemiology would in fact break
17 ovarian cancer into separate diseases, as I said in my
18 expert report and I said this morning.

19 Q. Now, you referenced the Reid and Sellers paper?

20 A. I did.

21 Q. To support your opinion regarding risk factors
22 for ovarian cancer?

23 A. Yes.

24 Q. In this paper not only their opinions regarding
25 risk factors but all the supporting epidemiological

1 studies there all look at risk factors as it relates
2 to the development of ovarian cancer, and you did not
3 state that this paper should be read with skepticism,
4 did you?

5 A. I said -- I did not state this paper should be
6 read with skepticism, no.

7 Q. But you did write studies including
8 epidemiological reports that treat ovarian cancer as a
9 single entity should in your opinion be viewed with
10 skepticism?

11 A. Yes. Both statements are correct.

12 Q. Now, there is a couple of other risk factors
13 that Reid and Sellers did not discuss, and that would
14 include, for example, Jewish ethnicity. Correct?

15 A. They did not discuss it.

16 Q. But it is biologically plausible for some woman
17 of Jewish ethnicity to get ovarian cancer?

18 A. If they have a BRCA mutation.

19 Q. And Reid et al did not discuss long-term genital
20 talc use as a risk factor for ovarian cancer?

21 A. They actually did discuss long term genital talc
22 use for ovarian cancer. It is on page 18. Can I read
23 it?

24 Q. Sure.

25 A. (Reading.)

1 "Mechanistic pathology in animal studies do
2 not support:

3 THE COURT: That's clearly not slow.

4 A. This is on page 18.

5 "While mechanistic, pathology, and animal
6 studies do not support evidence for the
7 carcinogenicity of talc on the ovarian epithelium
8 epidemiological studies have indicated an association
9 of talc use in increased ovarian cancer risk."

10 I agree with that. I agree completely with
11 Dr. Sellers' opinion. There is no animal,
12 mechanistic, pathological, or other evidence for an
13 effect of talc on the ovary epithelium, and I would
14 add the Fallopian tube epithelium to that.

15 Q. But there is epidemiological evidence?

16 A. There is some epidemiological evidence which she
17 discusses in this review, and I'm sure I read all of
18 those papers which was the subject of my expert
19 report.

20 Q. Now, when you were doing your initial PubMed
21 search and utilizing key words such as "ovarian
22 cancer," did you find a paper titled, "Opportunities
23 and Challenges in Ovarian Cancer Research, a
24 Perspective from the 11th Ovarian Cancer Action/HHMT
25 Forum, Lake Como, March 2007"?

1 A. I don't believe I read that.

2 Q. Have you ever seen this paper?

3 A. No. I'm just seeing it now. That's like
4 ancient history 2007.

5 Q. The Bible is from ancient history --

6 THE COURT: That's not appropriate. Let's
7 move on. We are talking science today.

8 Q. This was published in Gynecologic Oncology in
9 2008. Correct?

10 A. Yes.

11 Q. Not referenced in your expert report?

12 A. No.

13 Q. Not listed in your reliance list?

14 A. No.

15 Q. Not listed in your supplementary reliance list?

16 A. No.

17 Q. Has "ovarian cancer" in the title?

18 A. Yes, it does.

19 Q. If you go to the tab which is PSC Neel 24, they
20 write: "Identification of woman at increased risk
21 will facilitate prevention and early detection in
22 subsets of patients." As a physician, you would agree
23 that's a good thing to do. Correct?

24 A. Absolutely.

25 Q. Now, if you go on to the first page, the right

1 column, at the bottom of the first paragraph, this is
2 PSC Neel 24:

3 "Aside from genetic profiling there may be
4 reproductive or environmental risk factors which could
5 be combined to identify women at increased risk for
6 the disease. Such women might be candidates for more
7 intensive screening or chemo or immune prevention."

8 Did I read that correctly?

9 A. Yes.

10 Q. We just went through with the Reid and Sellers
11 paper reproductive and environmental risk factors, did
12 we not?

13 A. Yes.

14 Q. Which could be combined to identify women at
15 increased risk that's akin to smoking and asbestos,
16 and I think your co-carcinogenic risk factors
17 combining smoking, combining asbestos, you get a
18 higher risk than each agent by itself.

19 Do you understand that, sir?

20 A. Sure. Absolutely. Yes. Although it is not the
21 case all risk factors when combined would increase the
22 ability to prevent things. There could be
23 antagonistic effects, but just to be clear.

24 Q. That could be adjusted for in any
25 epidemiological studies?

1 A. Epidemiological studies are basically attempts
2 to do that. You have to do a prospective study to see
3 whether it is successful.

4 Q. To see what is successful?

5 A. Epidemiological studies can suggest a strategy,
6 but you have to do a prospective study to see whether
7 it actually works.

8 Q. You are saying that as an expert in
9 epidemiology?

10 A. As an expert in medicine.

11 Q. If I conducted a study retrospectively looking
12 at miners from the state of Colorado that both smoke
13 and are exposed to radon and look at their medical
14 history and I determine that smokers have an odds
15 ratio of 25 where as those exposed to radon have a
16 risk factor of four, and when combining them to affect
17 modification see a risk of 100, is that an invalid
18 study?

19 A. No. That's such a strong risk factor that it
20 makes a big difference. I misspoke.

21 Q. Let's go to the next paragraph which starts:

22 "A combination of demographic reproductive and
23 environmental risk factors might be used to develop a
24 model that would more accurately predict risk. One
25 preliminary algorithm using seven risk factors -- in

1 parenthesis age over 45, long-term genital talc use,
2 family history of ovarian cancer, early onset breast
3 cancer, Jewish ethnicity, no oral contraceptive OC
4 use, no live birth, no breast feeding, no tubal
5 ligation, show that women with six to seven of these
6 events have an odds ratio of 7.55."

7 Did I read that correctly?

8 A. Yes.

9 Q. Now, those risk factors that are listed there.
10 We just went through many with the exception of Jewish
11 ethnicity described in your reference 43, the
12 Reid/Sellers paper. Correct?

13 A. Yes.

14 Q. Now, OR equates to an odds ratio. Correct?

15 A. Yes.

16 Q. An odds ratio of 7.59 equates to an increased
17 risk of 659 percent. Correct?

18 A. I would have to do the calculation but I would
19 trust you.

20 Q. An odds ratio of 1 means no increased risk?

21 A. Yes.

22 Q. It's the background rate?

23 A. Yes.

24 Q. If we go up to 0 1.5 we have a 50 percent
25 increased risk.

1 A. Yes. I'm not contesting your math.

2 Q. Now, the co-authors of this paper -- the
3 conference was in 2007, the paper was published in
4 2008 -- reported on this algorithm indicating that a
5 woman with six to seven of these events, including
6 long-term genital talc use, had an increase of
7 659 percent of developing ovarian cancer, and you
8 didn't find this study, sir?

9 A. I remember seeing the study on that model. I do
10 remember seeing that study, but I don't remember in
11 detail what it said.

12 Q. Now, if we go down further in the paper we see a
13 list of authors.

14 A. Yes. I have the list.

15 Q. Now, at the second author is Frances Balkwill.
16 Frances. You know Dr. Balkwill?

17 A. Yes.

18 Q. You recognize her as an esteemed researcher in
19 the area of ovarian cancer?

20 A. Along with Dr. Boyd who is also listed as an
21 expert.

22 Q. That would be Jeffrey A. Boyd, who is a defense
23 expert?

24 A. Yes. Actually, I recognize most of them.

25 Q. In fact, you had Dr. Balkwill as one of your

1 lead speakers at the AACR meeting in 2012 that you
2 chaired. Correct?

3 A. Correct.

4 MR. RESTAINO: Your Honor, would this be a
5 good time to take a lunch break?

6 THE COURT: Yes.

7 THE DEPUTY CLERK: All rise.

8 (The luncheon recess is taken.)

9 (Continued on the next page.)

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A F T E R N O O N S E S S I O N

THE DEPUTY CLERK: All rise.

THE COURT: Thank you.

BENJAMIN G. NEEL, resumed

CROSS-EXAMINATION (continued)

BY MR. RESTAINO:

Q. Good afternoon, Dr. Neel.

A. Good afternoon.

Q. Dr. Neel,, I'm just going to finish off where we left, the studies regarding risk factors and the Lake Como studies, and I would like to put up on the screen your deposition testimony.

You were asked --

MS. SHARKO: I object. This isn't proper use of the deposition. There is no contradiction.

MR. RESTAINO: I think it is complete contradiction.

MS. SHARKO: I don't think it is proper use of deposition testimony.

THE COURT: Take it off. Ask him the question and see if he agrees with that. It will still happen, I'm sure.

1 BY MR. RESTAINO:

2 Q. Dr. Neel, can credible scientists look at the
3 evidence and determine the genital use of talcum
4 powder is a risk factor for ovarian cancer?

5 A. Not in 2019, no.

6 Q. That's because of the epidemiological studies
7 that have been published since then?

8 A. No, the biology studies that show no evidence of
9 causation.

10 Q. And you are relying strictly on biology studies
11 for that?

12 A. Those are the primary studies I reviewed as part
13 of my expert report.

14 Q. If there is a biology study that has an unknown
15 mechanism, you would not agree that study could
16 indicate carcinogenicity in a human being. Is that
17 true?

18 A. That's a hypothetical. I don't know what you
19 mean by a biological study without a mechanism.

20 Q. A molecular mechanism study.

21 A. I don't think there is any biologic evidence
22 talc causes ovarian cancer. Is that fair?

23 Q. Did you write your expert report with the same
24 care that you used in writing your published papers?

25 A. I tried to.

1 Q. You recognize there are some errors in your
2 expert report or misquotes as you used them so far
3 this morning? Have you had papers returned by
4 reviewers indicating that changes needed to be made?

5 A. Absolutely.

6 Q. In fact, it is not uncommon to send in a
7 published or a manuscript for publication to one
8 journal and have the journal, for whatever reason,
9 reject it and have it published in another journal.
10 Correct?

11 A. That's correct.

12 Q. That happens all the time actually?

13 A. Yes.

14 Q. Now, let's turn to your expert report. I'm on
15 page 53 of the outline -- your expert report on page
16 17, I believe, and it is paragraph B. You start off
17 with a quote, "MPO"?

18 A. Yes.

19 Q. "MPO and iNOS are highly expressed and
20 co-localized in EOC cells"?

21 A. That's referring to a quote from Dr. Saed's
22 paper.

23 Q. It is indeed. It is from Dr. Saed's report, the
24 bottom of page 5. And you write:

25 "Even if this statement were true," this

1 statement may in fact be true.

2 Correct?

3 A. I don't agree that it's true; but even if it
4 were true it's a non sequitur. That's what I wrote.

5 Q. The statement may be true?

6 A. No, that's not what I'm saying.

7 Q. You write, "Even if the statement were true" --

8 A. That's a hypothetical, if it were true, it's a
9 non sequitur. If you read the rest of it, you will
10 see it isn't.

11 Q. Let's go to Dr. Saed's report, the bottom of
12 page 5.

13 THE COURT: Is page 5 quoting from his expert
14 report or his manuscript?

15 MR. RESTAINO: The expert report.

16 Q. (Reading.)

17 "My laboratory has previously reported that
18 MPO, a hemoprotein present solely in myeloid cells
19 that acts as a powerful oxidant, and iNOS, a key
20 pro-oxidant enzyme, are highly expressed and
21 co-localized to the same cell in EOC cells."

22 A. I don't have his report, but I believe that's
23 what he wrote, yes.

24 Q. He has a reference there. Correct?

25 A. Yes.

1 Q. Reference 17, which is the paper published 2010
2 in Gynecologic Oncology?

3 A. Yes.

4 Q. A well-respected journal?

5 A. Yes.

6 Q. Now, you find this seriously flawed?

7 A. Yes.

8 Q. The peer reviewers did not?

9 A. They made a mistake, and there is knowledge
10 since that time that helps to address that mistake.

11 Q. The editor did not have a problem with this and
12 it was published. Correct?

13 A. Yes. There are many things published that are
14 not accurate.

15 Q. If this was seriously flawed, since this time in
16 2010, did you see a single letter to the editor of the
17 journal Gynecological Oncology pointing out serious
18 flaws in Dr. Saed's manuscript?

19 A. No.

20 Q. Did you write a letter to the editor at the time
21 indicating this paper had serious flaws?

22 A. I didn't read the paper at the time.

23 Q. You only read this paper after you were retained
24 as an expert by Johnson & Johnson. Correct?

25 A. This particular paper, that's correct.

1 Q. Are you planning on writing a letter to the
2 editor of the journal indicating this study has
3 serious flaws?

4 A. I hadn't thought about it.

5 Q. MPO is an oxidant and an inflammatory marker?

6 A. It is a pro-oxidant molecule inside of myeloid
7 cells, but it is not a marker of inflammation.

8 Q. Has it been shown in ovarian cancer to affect
9 proliferation and apoptosis?

10 A. Dr. Saed I believe claimed that, but it is not
11 expressed in ovarian cancer cells.

12 Q. Now, is your opinion that any effect on any cell
13 line by talcum powder is irrelevant?

14 A. No. It depends what the question is.
15 Irrelevant to what?

16 Q. Irrelevant to biological activity.

17 A. It depends on the context.

18 Q. Is it relevant to biological activity resulting
19 in inflammation?

20 A. Not if it concerns the ovarian cancer cell, no.

21 Q. Regarding the criticism of the SKOV-3 cell line,
22 in the same paragraph SKOV-3 is in fact still the most
23 widely used cell line for ovarian cancer. Correct?

24 A. I don't know if it is still. It depends on the
25 context.

1 Q. Have you seen any recent publications -- and
2 I'll limit it to 2018, 2019 -- advising the general
3 scientific community to not use SKOV-3 as a cell line
4 for study of ovarian cancer?

5 A. There are three papers published, but not in
6 2018, that did make exactly that advice.

7 Q. There are also papers that follow that in
8 response indicating the value of SKOV-3 for studying
9 ovarian cancer. Right?

10 A. I don't know which papers you are referring to.

11 Q. You didn't review both sides of those?

12 A. It is not two sides to that. It is
13 well-established from the genetic data that SKOV-3 is
14 not a serious ovarian cancer line. That is what the
15 controversy is about.

16 Q. What there is no controversy about, it is
17 generally accepted to test in that cell line for an
18 effect for ovarian cancer and then, if necessary,
19 check another cell line?

20 A. No, that's incorrect in my opinion.

21 Q. In your opinion?

22 A. Yes.

23 Q. Now, in paragraph C of your expert report on
24 page 18 you wrote:

25 "Common SNPs in the redox enzymes are known to

1 be strongly associated with altered enzymatic activity
2 that has been linked to ovarian cancer," and you put
3 pages 7 and 8, quoting Dr. Saed. Correct?

4 A. Correct.

5 Q. In fact, Dr. Saed does not state altered
6 enzymatic activity has been linked to ovarian cancer;
7 does he?

8 A. I don't have his expert report so I can't
9 comment on that.

10 Q. Let's turn to his expert report. And the
11 section entitled, "Common Polymechanism and Reduction
12 Enzymes Are Associated With Ovarian Cancer." What he
13 actually writes is:

14 "Common SNPs in the redox enzymes are known to
15 be strongly associated with an altered enzymatic
16 activity in these enzymes and helps explain the
17 enhanced redox state that has been linked to several
18 malignancies including ovarian cancers."

19 Correct?

20 A. That's what he wrote, yes.

21 Q. This has been generally accepted by the
22 scientific community?

23 A. No, it has not.

24 Q. Dr. Saed provide two references for this
25 statement which are not in your expert report?

1 A. I don't have the references in front of me, so I
2 can't comment on those references. If you want to
3 give me his expert report, I would be happy to help.

4 THE COURT: We can get it from chambers.

5 MS. O'DELL: Judge, that would be helpful.

6 (Pause.)

7 THE COURT: You are checking the cites 12 and
8 16.

9 THE WITNESS: Reference 12 is Dr. Saed's own
10 paper and reference 16 is a paper about -- I haven't
11 read that paper but that's not relevant to the
12 question whether these SNPs are linked to a redox
13 state. I don't believe this paper has anything to do
14 with those SNPs. In any event, those SNPs are not
15 associated with ovarian cancer which is what I was
16 writing.

17 BY MR. RESTAINO:

18 Q. Doctor, you didn't read this. The first one is
19 published in Reproductive Sciences and the second one
20 is published in Gynecologic Oncology, two peer-
21 reviewed journals. They have been peer-reviewed and
22 published. Right?

23 A. As I recall, I think you asked me if it has been
24 validated by others. The first paper is Dr. Saed's
25 paper. That's not "others." The second paper, I

1 don't remember if I read it or not, but I don't
2 believe that has anything to do with the SNPs. And I
3 checked for the SNPs, which is what I was writing
4 about in that paragraph.

5 Q. Doctor, there is nothing wrong with quoting
6 one's previous work from a laboratory, and that
7 happens all the time?

8 A. Absolutely. I wasn't questioning that. You
9 said by others and I was answering that.

10 Q. Once it is published, are there any letters to
11 the editor in any of these journals pointing out flaws
12 or errors in these papers?

13 A. Not to my knowledge.

14 Q. Paragraph E on page 20 of Dr. Saed's expert
15 report -- I'm sorry -- of your expert report.

16 A. Yes, I see it.

17 Q. You wrote: "Talc initiates an inflammatory
18 response." Page 10-11. Is that correct?

19 A. Yes.

20 Q. Now, if you actually go to Dr. Saed's report
21 from that section, he writes:

22 "Asbestos fibers in the lung initiate an
23 inflammatory and scarring process, and it has been
24 proposed that ground talc as a foreign body initiates
25 a similar inflammatory response, and it has been

1 proposed that ground talc as a foreign body might
2 initiate an inflammatory response."

3 Isn't that correct?

4 A. That's what he writes, yes.

5 Q. That's fundamentally different than what you
6 wrote as a synopsis of saying talc initiates an
7 inflammatory response. Correct?

8 A. I don't think so, no.

9 Q. As you wrote it, and in your experience as a
10 peer reviewer and editor, this would not be accepted
11 for publication in a peer-reviewed journal, the way
12 you mischaracterize that full sentence by Dr. Saed?

13 A. I don't think this mischaracterizes the sentence
14 insofar as it appears to talc. If you believe it was
15 a mischaracterization, I apologize. That's not what
16 my intent was, to mischaracterize his statement.

17 Q. Now, if we go to paragraph G of your report,
18 page 21, you write:

19 "Migration/transport of particles through the
20 genital tract is universally accepted."

21 Correct?

22 A. Yes.

23 MR. RESTAINO: I'm going to withdraw the
24 question. I didn't strike that out.

25 Q. If you go to your expert report, page 23,

1 paragraph K, in the middle of the paragraph you write:

2 "He does not seem to be aware of recent
3 evidence that full blown cancers are often more
4 sensitive to oxidative stress. Reference 12. Indeed,
5 one therapeutic approach under investigation in
6 several laboratories is to promote increased oxidative
7 stress in cancer cells."

8 Did I read that correctly?

9 A. Yes, you did.

10 Q. Now, reference 12 is the two phases of reactive
11 oxygen species in cancer?

12 A. Yes.

13 Q. They write there:

14 "Reactive oxygen species is not appreciated
15 for their cellular signalling capabilities for having
16 a dual role in cancer."

17 Isn't that true?

18 A. I don't remember the paper by heart. Can you
19 please tell me where to find it and we can discuss it.

20 Q. Let me ask you --

21 A. I'll agree with that statement.

22 Q. You would agree with it?

23 A. Yes.

24 Q. And yet on the one hand ROS can promote
25 protumorigenic signalling. Correct?

1 A. In certain cells, yes.

2 Q. That would facilitate cell proliferation?

3 A. That's a little more complicated than that. I
4 don't think that's exactly an accurate statement as
5 you've made it. Definitely in certain contexts,
6 oxidative stress can contribute to cancer.

7 Q. Do you agree that ROS can promote and facilitate
8 cancer cell proliferation?

9 A. Not directly. Indirectly.

10 Q. Resulting in cellular proliferation?

11 A. All cancer cells proliferate. You are
12 oversimplifying a complex issue with respect.

13 Q. Do you remember in your expert report, from what
14 I'm reading, you have a reference 12. Correct?

15 A. Yes.

16 Q. Do you know what reference 12 is?

17 A. Not by heart. I'll have to look it up.

18 Yes, I know the paper and know the author.

19 Q. They state therein that ROS can promote cellular
20 survival also. Correct?

21 A. Indirectly by causing mutations.

22 Q. And adaptation to hypoxia?

23 A. Yes.

24 Q. On the other hand, ROS can promote anti tumor
25 genetic signalling and trigger oxidative-induced

1 cancer cell death?

2 A. Yes. That's what I was referring to in that
3 sentence.

4 Q. When you indicate Dr. Saed does not seem to be
5 aware of recent evidence that full-blown cancers are
6 often more sensitive to oxidative-stress, citing this
7 paper, this paper does indicate there are the two
8 sides of the coin.

9 A. Yes. I'm aware of both sides.

10 Q. And Dr. Saed is pointing out one side of that
11 coin?

12 A. Yes. But he's not pointing out the other side.
13 He was implying, I believe, in the context I was
14 writing that he was implying oxidative stress is
15 always good for cancer cells.

16 Q. Is that what Dr. Saed's manuscript states?

17 A. Yes. In my opinion, yes.

18 Q. In your opinion?

19 A. Yes.

20 Q. Now, if we could turn to your expert report,
21 page 22.

22 A. Yes.

23 Q. You write:

24 "Similarly, Reviewer Two noted that, quote,
25 their data do not show, despite the author's claim,

1 any evidence that these cells are transformed, i.e.
2 malignant... Consequently, neither tumor initiation
3 nor progression is documented in this study as opposed
4 to the statement in highlight No. 1 in the text and
5 elsewhere."

6 Did I read that correctly?

7 A. Yes.

8 Q. Now, if we put up what Reviewer Two actually
9 stated, you see they write:

10 "Their data do not show, despite the author's
11 claim, any evidence that these cells are transformed"
12 -- however you leave out -- "specifically, no
13 experiments documenting changes in cell survival,
14 proliferation, or resistance to apoptosis have been
15 performed." Correct?

16 A. Yes.

17 Q. And you didn't include that sentence in your
18 expert report. Correct?

19 A. I don't think it changes the context of my
20 statement.

21 Q. Would it change the context of your statement if
22 in fact those studies were in fact performed?

23 A. No, because the last statement is still true.

24 Q. Do you know if in the published final manuscript
25 by Fletcher and Saed, if in fact they documented

1 increased cell proliferation and decreased apoptosis
2 as this Reviewer No. 2 recommended.

3 (Pause.)

4 A. Yes. In the finally published manuscript are
5 experiments that purport to examine those questions
6 but both of the experiments are seriously flawed in my
7 opinion.

8 Q. Have you written a letter to the editor pointing
9 out that those observations are flawed in your
10 opinion?

11 A. No.

12 Q. Has anyone written to the journal?

13 A. Not that I know of.

14 Q. Doctor, Dr. Saed never said that CA-125
15 indicated the pathogenesis of ovarian cancer, did he?

16 A. He said it was a hallmark of ovarian cancer.
17 That may be a misstatement or may be a
18 misunderstanding on my part what he misrepresents by
19 hallmark.

20 Q. Do you consider CA-125 to be the gold standard
21 tumor marker in ovarian cancer?

22 A. For monitoring the amount of tumor, yes.

23 Q. And do you agree the pathogenesis and
24 development of ovarian cancer have been closely linked
25 to inflammatory process?

1 A. Could you repeat the question a little bit
2 slower. I'm not sure I followed that.

3 Q. Would you agree the pathogenesis and development
4 of ovarian cancer have been closely linked to an
5 inflammatory process?

6 A. If by pathogenesis and development you mean once
7 the cancer is established that it is linked to
8 inflammation, I think that is an accurate statement.
9 If you mean inflammation has been shown to induce or
10 initiate ovarian cancer, I think that remains in the
11 realm of hypothesis or speculation.

12 (Pause.)

13 Q. Doctor, are you familiar with the study, the
14 Balkwill and Mantovani article?

15 A. Yes, it is a review article.

16 Q. Titled, "Inflammation and Cancer Back to
17 Virchow."

18 A. Yes. I am familiar with the paper.

19 Q. And you are familiar with Dr. Balkwill and Dr.
20 Mantovani.

21 This is published in the Langseth?

22 A. In 2001.

23 Q. Now, if you turn to panel one of the document.

24 A. What exhibit is that, please?

25 Q. Seven. Panel 1 now. It should be on here.

1 MR. RESTAINO: We'll move on. I'll strike it.

2 Q. Doctor, are you familiar with the National
3 Cancer Institute?

4 A. Yes.

5 Q. Does the National Cancer Institute, to the best
6 of your knowledge, associate asbestos with the
7 formation of malignant mesothelioma, pleural
8 peritoneal, and ovarian cancer?

9 A. I believe that's in the PDQ link for ovarian
10 cancer.

11 Q. Now, if we have PSC 19, and this is a review
12 article. The author is Sekido out of the Division of
13 Molecular Oncology in Japan; again, a review article
14 as we discussed, typically written by someone learned
15 in the area. Correct?

16 A. It depends on the journal in which it is
17 published.

18 Q. Now, if we move down to page 1, the right
19 column, second full paragraph, they have a section
20 there, "Genetic Damages Induced By Asbestos."

21 A. I got it.

22 Q. See the second paragraph they write:

23 "After long and thin asbestos fibers are
24 inhaled deeply into the lung and penetrate the pleural
25 space, interaction of asbestos fibers with

1 mesothelioma cells and inflammatory cells are thought
2 to initiate prolonged cycles of tissue damage, repair
3 and local inflammation which finally lead to
4 carcinogenesis of MM," which they describe as
5 malignant mesothelioma "with unknown mechanisms."

6 Did I read that correctly?

7 A. Yes.

8 Q. To the best of your knowledge, is there a known
9 mechanism by which asbestos fibers today cause the
10 cancers of the pleural space?

11 A. I'm not an expert in mesothelioma, and I can't
12 comment in an intelligent way on that question at all.

13 Q. When you went through the Bradford Hill view
14 points, one of the viewpoints is analogy. Correct?

15 A. Yes.

16 Q. You would agree analogy to other conditions
17 could be important for an investigator?

18 A. It would be one of the factors one would weigh
19 in coming to a conclusion.

20 Q. For example, in today's day and age, it would be
21 incumbent upon a company who is coming up with a new
22 medication to treat morning sickness in women to be
23 aware of what happened with thalidomide?

24 MS. SHARKO: Objection. This is well beyond
25 the scope of what we are here for, the obligation of a

1 company to do something.

2 THE COURT: I think phrasing in the context of
3 the company is not appropriate in your question.

4 Go ahead.

5 Q. In today's day and age --

6 THE COURT: Put it in that context, thank you.

7 BY MR. RESTAINO:

8 Q. Thalidomide is associated with phocomelia, or
9 something like that.

10 In this case we have a known substance
11 recognized by NCI causing cancer in the lung pleural
12 cavity, peritoneal and in the ovary inducing
13 inflammation, but the exact mechanism is unknown.

14 Doctor, does that mechanism have to be known
15 for one to assume and recognize that asbestos causes
16 ovarian cancer?

17 A. First of all, I didn't make any statement as to
18 whether asbestos causes ovarian cancer.

19 Second of all, I did not make any statement as
20 to whether there has to be an expert on mesothelioma,
21 so I can't comment on that on an intelligent way.

22 Q. Doctor, you didn't provide testimony on your
23 knowledge of any of the constituents that are found
24 and reported to be found in talc. Correct?

25 A. I'm not sure I understand your question. Maybe

1 I can answer it in a way that will be clear. What I
2 said was I wasn't aware of any information about the
3 constituents.

4 Q. And have you undertaken any research since the
5 time of your deposition to determine what constituents
6 are found within talc powders?

7 A. No.

8 Q. Do you know if asbestos is present?

9 A. No, I don't know one way or the other.

10 Q. Do you know if any form of asbestos is present?

11 A. I don't know one way or the other.

12 Q. Do you know if fragrances are present?

13 A. I don't know one way or the other.

14 Q. Do you know if heavy metal is present?

15 A. I don't know one way or the other.

16 Q. Isn't it important that you are going to be
17 evaluating the potential carcinogenic effect of a
18 substance that you know whether or not a known
19 carcinogen is within that substance?

20 A. No, not in my opinion, no.

21 Q. So if someone came to you as the director of
22 your Cancer Institute and asked you to conduct a study
23 looking at the carcinogenic effect of their paint,
24 wouldn't one of the seminal questions be: Well, is
25 there lead in your paint? Because if so there is an

1 increased risk of liver and esophageal cancer?

2 A. No. That would not be relevant if I were
3 actually going to do a study to test the substance.
4 That's what biological plausibility means.

5 Q. Without the presence of lead, it is true, is it
6 not, you keep getting negative results? Because the
7 known carcinogen is absent?

8 A. I don't know -- you asked me if I was going to
9 test something. I told you how I was going to test.
10 Can you clarify.

11 Q. If you wanted to establish a study that showed
12 no evidence of carcinogenicity for a particular form
13 of paint, one could say: I want just lead-free paint;
14 and, lo and behold, look, there is no cancer here.
15 Correct?

16 A. That's incorrect on multiple levels in my
17 opinion.

18 First of all, I wouldn't design a study to
19 show something. I would design a study to test
20 something. You said if somebody came to me with a
21 substance and asked me to test it, would I know what's
22 in it. The only reason I would need to know what's in
23 it is if I thought it was potentially dangerous to the
24 people who are going to be doing the experiments. But
25 I wouldn't need to know what's in it to do the

1 experiment and get the result.

2 Q. So if you did this experiment with paint not
3 knowing if there is any lead in it, and the experiment
4 was negative, then you would say there is no
5 carcinogenic effect associated with this substance.
6 Would that be a valid study?

7 A. It would be a valid study for the question you
8 asked me to address, which is: Is this substance
9 carcinogenic? And that's what I would do, yes.

10 Q. Now, if you tested it and it had lead in it, and
11 it had a different effect, wouldn't that be important
12 for you to know?

13 A. If I tested it, I would know it. I don't
14 understand the question.

15 Q. If you tested the substance that had lead in it,
16 and you saw a carcinogenic effect, you would come to
17 the conclusion there is carcinogenicity going on here.
18 Correct?

19 A. Yes.

20 Q. If you tested a substance with no lead in it,
21 you would say there is no carcinogenicity study.
22 Correct?

23 A. That would be the correct study. There would be
24 no carcinogenicity to that substance.

25 Q. Now if you were given an unknown substance and

1 you don't know it has lead in it, and it comes out
2 with no carcinogenic effect, how could you say there
3 is no carcinogenic effects without knowing there is
4 potentially the presence of a carcinogen in it?

5 A. With respect Mr. Restaino, you can't prove a
6 negative. You can only test a hypothesis. Beyond
7 your question. That's not the scientific method. The
8 scientific method is pose a hypothesis, design an
9 experiment, do the experiment and decide what the
10 experiment shows you. That's the scientific method.

11 Q. And in that method, one must adjust potential
12 and known confounders. Correct?

13 A. Confounders is not a term of biology.
14 Confounders is a term of epidemiology. If you are
15 asking me about biology, I don't know what you mean by
16 "confounders." You have to control for all of the
17 issues in that experiment. And in this experiment,
18 the hypothetical experiment you have outlined to me,
19 you would take a substance, you would test it in the
20 right assay with proper replicate and proper controls,
21 and then you would make proper measurements again with
22 validated assays, and you would come to a conclusion.
23 That is the scientific method -- at least a scientific
24 method of a cancer biologist. And I'm a cancer
25 biologist, so I can give you my opinion on that. I

1 hope that's helpful.

2 Q. We'll move on.

3 You said you reviewed a study by Dr. Shih.

4 Correct?

5 A. Yes.

6 Q. That study by Dr. Shih has not been published?

7 A. That's correct.

8 Q. That study by Dr. Shih is not complete.

9 Correct?

10 A. I don't know that this not complete. I have no
11 information one way or the other.

12 Q. Did you review his deposition?

13 A. I don't think I read his deposition actually.

14 Q. Did you discuss his deposition with anyone?

15 A. No. I wouldn't discuss it with anybody if I
16 hadn't read it. It would be hard to discuss.

17 Q. And Dr. Shih obtained histopathology slides from
18 a grant, and the slides include evidence of ovarian
19 cancer, normal ovarian tissue, Fallopian tissue.

20 Correct?

21 A. Yes.

22 Q. And Dr. Shih looked in the slides and observed
23 those slides that had evidence of STICs. Correct?

24 A. Yes, and p53 signatures to be complete. It also
25 had p53 signatures in that, yes. There were several

1 samples that had p53 signatures.

2 Q. And he looked for evidence of inflammation?

3 A. Yes.

4 Q. And he looked for inflammation as evidenced by
5 the presence or absence of lymphocytes. Correct?

6 A. It was the presence and absence of macrophages,
7 neutrophils and lymphocytes.

8 Q. Did he list presence of macrophages and
9 neutrophils in his report?

10 A. I don't recall, to be honest. That was my
11 recollection, but I haven't read that in a while,
12 maybe a week.

13 Q. Because macrophages as we discussed are another
14 marker of inflammation?

15 A. Macrophages are normal cell types, so they are
16 not by themselves a marker of inflammation. Excessive
17 macrophages in full penetration into tissues would be
18 a marker of inflammation.

19 Q. Lymphocytes are a marker of inflammation?

20 A. Again, to be clear, lymphocytes are normal cells
21 in the body, and excessive accumulation of lymphocytes
22 could be a marker of inflammation. It's the excess
23 that's the critical point.

24 Q. In fact, that's what Dr. Shih was looking for,
25 the evidence of inflammation. Correct?

1 A. Correct.

2 Q. His hypothesis was that if the STICs are
3 developing as a result of inflammation, there must be
4 inflammation around them. Correct?

5 A. I believe that was his hypothesis, yes.

6 Q. But if he did not see an increased number of
7 lymphocytes and did not report whether there were
8 macrophages or any other cells associated with the
9 innate and adaptive immunity, that alone doesn't tell
10 us that there is no inflammation present. That just
11 tells us there is no increase in lymphocytes.
12 Correct?

13 A. Again, I would have to look at his report. If
14 you want to give me his report and the study. I don't
15 feel comfortable commenting from memory on that.

16 Q. If one is looking for signs of inflammation and
17 one says, I do not see an increased number of
18 lymphocytes, but I don't report the number of
19 macrophages, neutrophils, NK cells, and all the cells
20 associated with the innate and adaptive process, all
21 that tells you, there is not an increase in
22 lymphocytes; it doesn't tell you there is not an
23 increase in inflammation. Wouldn't you agree?

24 A. It doesn't say there is an increase in those
25 other cell types. I'll agree with that.

1 Q. Did Dr. Shih have access to the medical records
2 from the woman in which these slides came from?

3 A. I don't recall.

4 Q. That would be important; would it not?

5 A. Important for what?

6 Q. Well, if we are going to say there is no
7 evidence of increased lymphocytosis, if there is no
8 increase in lymphocytes, wouldn't one want to know if
9 the patients from which they came had underlying
10 medical conditions that were being treated with
11 medications known to decrease lymphocyte counts?

12 A. Not if the question is whether there is any
13 evidence or inflammatory cells in STICs. That's the
14 question. He was asking whether in 43 cases that he
15 saw of STICs or p53 signatures, if whether there was
16 any indication of inflammation, and that's what the
17 study was addressing.

18 Q. Limited to his observation of the number of
19 lymphocytes?

20 A. As I said, I can't testify honestly to that
21 without seeing the report.

22 Q. Let's assume for a moment the study was limited
23 just to the presence of lymphocytes. He doesn't know
24 if the patient from which that study came was on
25 tegretol, which is known to cause decreased lymphocyte

1 counts. You don't know that, do you?

2 A. You would have to speculate a large number of
3 the patients were on that because he looked at
4 43 cases.

5 Q. Of those 43 patients, we don't know how many of
6 those patients had heartburn and were going across the
7 street to take Tagamet, do we?

8 A. No.

9 Q. We don't know if any of them had a prior organ
10 transplantation, and they were on organ rejection
11 medication, which reduces the immune response.
12 Correct?

13 A. Yes.

14 Q. And we also don't know how many of those STICs
15 that he observed, that were devoid of evidence of
16 inflammation around them, were actually metastatic
17 cells from elsewhere, whether the Fallopian tube or
18 anywhere else, because there is publication showing up
19 to 25 percent of STIC are seen in the ovary are
20 metastatic?

21 A. I'm extremely familiar with that publication,
22 and you are misstating the evidence completely because
23 those patients would have had ovarian cancer, and he
24 discriminated in his study between patients with
25 ovarian cancer and patients with STICs, and the STICs

1 he looked at were STICs from patients are without
2 evidence of ovarian cancer.

3 Q. If you are familiar with that study, you know
4 they did. And I'm going blank on the exact name of it
5 -- is it genomic testing?

6 A. Genomic analysis, yes.

7 Q. It would tell you from whence in the body the
8 cell came?

9 A. It's a paper by Lengyel, and he is a well known
10 ovarian cancer researcher from Chicago, and that was
11 studying whether some STICs were metastatic ovarian
12 cancer cases. That was the study.

13 Q. I believe I'm referring to another. I want to
14 ask you this:

15 Do you have an opinion as to whether or not
16 some percentage of STICs that can be observed in the
17 ovaries of women have actually come from elsewhere?

18 A. Yes. Can I elaborate? You are asking it
19 completely out of context.

20 Q. If those STIC lesions came from elsewhere, we
21 really don't know if inflammation caused those STIC
22 elsewhere and they then migrated?

23 A. That's not what happens. I think you are
24 misstating the way that things actually happen.

25 The studies that show some STICs can be

1 metastatic show that they come from a widely
2 metastatic tumor. You wouldn't expect to see a STIC
3 in a patient without a relatively obvious cancer and
4 that patient would have been excluded from Dr. Shih's
5 study.

6 Furthermore, there is no question that fully
7 blown ovarian cancer is associated with inflammation;
8 and, so, if anything, a metastatic STIC would be much
9 more likely to have inflammation associated with it
10 than not. So I don't accept the premise of your
11 question.

12 Q. Do you know if Dr. Shih was unable to account
13 how many of the STICs he observed came from elsewhere
14 in the body?

15 A. As I tried to answer, he said these were from
16 patients without ovarian cancer. So this was a study
17 -- this study I'm pretty familiar with. It was a
18 large scale study which our institution when I was in
19 Canada at Princess Margaret Hospital participated in,
20 and it collected a large number of samples from
21 patients with ovarian cancer and other patients, and
22 that was what the study was about. I think it was the
23 DOD academy study.

24 MS. SHARKO: Your Honor, I think we are a
25 little past the two-hour mark.

1 THE COURT: How much longer do you have?

2 MR. RESTAINO: How much longer are you going
3 to give me?

4 THE COURT: We're a little earlier than
5 yesterday. So I'll give you a little more time.

6 BY MR. RESTAINO:

7 Q. Doctor, the STICs are serous lesions?

8 A. Precursor lesions for high grade serous ovarian
9 cancer but they are early lesions.

10 Q. Are they associated only with the high grade
11 serous ovarian cancer?

12 A. Yes.

13 Q. Group 1?

14 A. Type II tumors.

15 Q. They are not what you would call the Group 1?

16 A. Correct.

17 Q. Do you agree a lack of inflammation with STIC
18 tells us nothing about the pathogenesis of Group 1
19 ovarian cancer?

20 A. Can we use the term Type I.

21 Q. Let's talk about what you call Type I or ovarian
22 cancers. These are primarily the high grade tumors.
23 Correct?

24 A. No, exactly the opposite. Type II tumors are
25 the high grade tumors. Type I tumors are more often

1 the ones that come from endometriosis.

2 Q. You would agree 60 percent and possibly all of
3 the high grade serous ovarian cancers originate in the
4 Fallopian tube?

5 A. I think you are quoting my report.

6 Q. Do you agree?

7 A. That's an example where I did consider both
8 sides of the question. Actually, many ovarian cancer
9 researchers are firmly convinced 100 percent of high
10 grade serous cancers come from the Fallopian tube, and
11 the evidence is still not that strong. That's why I
12 couched that.

13 Q. If inflammation caused the initial mutation,
14 wouldn't that inflammation be found in the Fallopian
15 tube?

16 A. What do you mean "the initial mutation"?

17 Q. The inflammation that led to the DNA errors
18 which leads to mutagenesis and carcinogenesis.

19 A. What's the question?

20 Q. If inflammation initiated this cascade leading
21 to the Type II high grade which originated in the
22 Fallopian tube, you would expect to see it in the
23 Fallopian tube. Correct?

24 A. Yes.

25 Q. Did Dr. Shih look in the Fallopian tube?

1 A. Yes. He looked in STICs which are in the
2 Fallopian tube, in the fimbria.

3 Q. For the remaining 40 percent where you wrote "no
4 precursor lesion can be identified," so there is no
5 specific site where scientists can even look for
6 inflammation. Correct?

7 A. Again, I did write that, but in the context of
8 your question, it is a little bit misleading. So,
9 again, in the studies that have been done thus far,
10 the studies look for synchronous lesions in patients
11 with ovarian cancer and Fallopian tubes that were not
12 completely involved in the cancer. And in those cases
13 they could in 60 percent of the cases find a precursor
14 lesion, a STIC, if you will, and they check to see
15 whether the STIC had the same mutation or in some
16 cases mutations as in the ovarian cancer. That
17 doesn't really mean that there is no precursor lesion
18 in the other 60 percent. It just means that, for
19 example, the tumor was so developed that it encased
20 the Fallopian tube and you couldn't find the original
21 precursor lesion. That's what it means. Just to be
22 clear.

23 THE COURT: Do your timing by 2:30, please.

24 MR. RESTAINO: Yes, your Honor, thank you.

25 BY MR. RESTAINO:

1 Q. Doctor, you testified this morning that p53
2 deactivation is the sine qua non of what you call Type
3 II ovarian cancers which include the high grade. Is
4 that correct?

5 A. p53 mutations is what I said. Some of the
6 mutations are neomorphic activity, and they are
7 inactivating p53 function, but they are interfering
8 with two other tumor suppressors, and I was trying to
9 make it simple because it is very complex.

10 Q. Doctor, the p53 gene, when it becomes mutated,
11 is a oncogene?

12 A. P53 is generally termed the tumor suppressor
13 gene.

14 Q. Mutated p53 is by definition --

15 A. That's an argument that one can have.

16 Q. But you indicate in your report Dr. Shih doesn't
17 have a basic knowledge of biology because he called
18 p53 an oncogene in his deposition, right?

19 A. It was the context he used the term. If you
20 want to go to that part, I would show you why that's
21 true.

22 THE COURT: Dr. Shih or Dr. Saed?

23 THE WITNESS: Dr. Saed?

24 A. You meant Dr. Saed.

25 Q. Dr. Saed. I apologize.

1 Now, if you were asked on direct examination
2 about the Buz'Zard study?

3 A. Yes.

4 Q. You stated the paper was not consistent with
5 Dr. Saed's data and conclusions?

6 A. That's correct. Not in detail. If you look in
7 detail at the actual data.

8 Q. If you look at the Buz'Zard data they have the
9 same dose of talc Dr. Saed found ROS that were
10 actually lower than the treated cells in the
11 controlled. Correct?

12 A. One of the doses they used was the same as
13 Dr. Saed used, yes.

14 Q. If you look at the Buz'Zard scientists actually
15 found -- if we looked at A 16, which is the Buz'Zard
16 2007.

17 A. Yes.

18 Q. Turning to page 5, Figure 3, the authors
19 reported, "the ROS generation of ovarian epithelial
20 cells, granular ovarian cells had the effects over
21 time." Correct?

22 A. Yes.

23 Q. Their report results in the paragraph below.
24 Correct?

25 A. Yes.

1 Q. And they write that "Talc caused an initial dose
2 dependent decrease in ROS generation."

3 You stated that, correct, in your report. You
4 discussed that?

5 A. I don't believe I expressed that detail in my
6 report. I stated it this morning in response to
7 Ms. Sharko's questions.

8 Q. Now, the talc caused an increase in ROS with
9 time; did it not?

10 A. Can we actually look at the data instead of
11 their statement? We just looked at the data. I'll be
12 happy to point out my point. Let's look at the figure
13 you put up.

14 Q. It is page 5, Figure 3.

15 A. If you look at the panel that says 100-microgram
16 per mill dose, which is the dose Dr. Saed used 24 and
17 72 hours, which hours -- 72 hours is, I believe, the
18 time of Dr. Saed's experiment, and you compare it to
19 the 0., you will notice both at 24 hours of talc and
20 72 hours of talc, the ROS has measured directly by ECF
21 staining, which is a standard assay for measuring ROS
22 is decreased. That's what I said in response to
23 Ms. Sharko's question this morning.

24 Q. It was decreased, but other times it was
25 increased?

1 A. No. Every time point at a hundred it is
2 decreased. Even at the 120 point.

3 Again, with respect, if I can clarify, this
4 morning -- yesterday Dr. Saed said that you don't need
5 to measure ROS levels directly. You can simply infer
6 them or deduce them from measuring the level of pro
7 and antioxidants in the cell. And I said that that
8 wasn't true in my report. I think this is a good
9 example of why what I said was accurate.

10 Furthermore, the statement that the Buz'Zard
11 paper supports Dr. Saed's study is repudiated or
12 questioned by this data, isn't it?

13 Q. It is not your opinion that over time these
14 levels increased?

15 A. I don't think it is a matter of opinion. If you
16 simply look at the data, you can see that in the 100
17 point, which is what Dr. Saed did, all time points in
18 the study is reduced. That's not an opinion. That's
19 data.

20 Q. Now, I want to finalize that some of your
21 opinions and used examples of, that certain
22 inflammatory disease are not associated with cancer?

23 A. I didn't say that.

24 Q. You didn't say rheumatoid arthritis is not
25 associated with levels of cancer?

1 A. I said it wasn't clearly associated with ovarian
2 cancer to my knowledge.

3 Q. I stand corrected. It is not associated with
4 ovarian cancer. Rheumatoid arthritis is in fact an
5 inflammatory arthritic condition. Correct?

6 A. Yes.

7 Q. And rheumatoid arthritis has been associated
8 with other forms of cancer?

9 A. Perhaps I can't remember in detail whether
10 that's true or not. I wouldn't be surprised, though.
11 I'm not testifying as to that. I'm testifying as to
12 ovarian cancer.

13 Q. However, it is the inflammatory effect that I'm
14 focusing in on. It is associated with Hodgkin's and
15 nonHodgkin's lymphoma, is it not?

16 A. Yes, but that's misleading in terms of the
17 conclusion because Hodgkin's disease is a disease of
18 the lymphocytes. So it is a little -- that's the
19 innate and inactive immune system interacting. So
20 it's not analogous to an epithelial cancer.

21 Q. You mentioned SLE in your expert report?

22 A. Correct.

23 Q. And you said it was not associated with ovarian
24 cancer?

25 A. Not to my knowledge.

1 Q. And SLE is an auto inflammatory immune disease?

2 A. Yes.

3 Q. And SLE is in fact associated with other forms
4 of cancer including nonHodgkin's lymphoma?

5 A. What you are saying is true, but it misstates
6 the connections. But it is part of the immune system,
7 so it is not surprising a frequently stimulated immune
8 system may lead to an immune cancer.

9 Q. You write psoriatic arthritis is also not
10 associated with ovarian cancer?

11 A. As far as I know, no.

12 Q. But the inflammatory process of psoriatic
13 arthritis is associated with the development of cancer
14 elsewhere?

15 A. Again, cancer is not one disease.

16 Q. And you also said NSAIDS, non-steroidals are not
17 associated with a decrease in the incidence of ovarian
18 cancer. Correct?

19 A. That's correct.

20 Q. The implication being if in fact ovarian cancer
21 is caused by inflammation, individuals taking an
22 NSAID, Aleve, would have a decreased incidence of
23 ovarian cancer?

24 A. That was not my implication. That may be your
25 inference.

1 Q. You state it is not associated with a decreased
2 risk?

3 A. That's correct.

4 Q. And you put in several references?

5 A. Yes.

6 Q. Aspirin is a form of a non-steroidal anti-
7 inflammatory drug. Correct?

8 A. That's correct.

9 Q. And aspirin is associated with a decreased risk
10 of ovarian cancer?

11 A. That's a very complex issue which you reduced to
12 a sound bite which is not exactly accurate. Can I
13 elaborate?

14 Q. Sir, in the last minute I have, if you can look
15 at PSC Neel 14. That's the associations between
16 aspirin use and risk of cancer meta-analysis.

17 Q. Sir, in the abstract you can see this is a
18 meta-analysis of observational studies.

19 "We have conducted an updated meta-analysis to
20 assess the associations between aspirin use and
21 cancers."

22 And under "results" 218 studies, you see
23 "aspirin use was associated with a significant
24 decrease in the risk of overall cancer, relative risk
25 0.89," and going down a couple of more lines,

1 "ovarian" with a relative risk of 0.89.

2 "These findings suggest that aspirin use is
3 associated with a reduced of gastric, esophageal,
4 colorectal, pancreatic, ovarian, endometrial, breast,
5 and prostate cancers and small intestine
6 neuroendocrine tumors."

7 A. Yes. But if you look in detail at the paper and
8 the follow-up paper which was published in 2019, it
9 shows the effect of aspirin is only for people who use
10 it every day, and only over a certain time period, and
11 not people who use it four times a week, and only at
12 the lowest doses, and aspirin has other effects NSAIDs
13 don't have.

14 In particular, low dose aspirin affects
15 platelets, and platelets have an independent possible
16 effect on ovarian cancer. So the fact that aspirin at
17 low doses, given with very defined dosing intervals
18 has an effect, does not really give you much
19 information about inflammation in ovarian cancer, in
20 my opinion.

21 Q. But the aspirin is shown in association with
22 decrease risk of these studies and aspirin is a
23 non-steroidal inflammatory drug?

24 A. Again, you are cherry-picking, in my opinion, a
25 small piece of a study and trying to come to a general

1 conclusion. Your statement is, as stated, correct,
2 but the implications are not correct in my opinion.

3 THE COURT: Thank you.

4 MR. RESTAINO: Thank you for your indulgence.

5 THE COURT: No problem.

6 MS. SHARKO: I have a very short redirect.

7 Can I have five minutes?

8 THE COURT: Sure.

9 THE DEPUTY CLERK: All rise.

10 (Recess.)

11 (Continued on the next page.)

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1 THE DEPUTY CLERK: All rise.

2 THE COURT: Thank you.

3

4 **BENJAMIN G. NEEL**, resumed.

5

6 REDIRECT EXAMINATION

7 BY MS. SHARKO:

8 Q. Dr. Neel, let's take a look at Exhibit 16, the
9 Reid paper that Mr. Restaino used on
10 cross-examination.

11 First of all, is Reid a review article or is
12 it an epi study?

13 A. It's a review article.

14 Q. Secondly, do you need to have biologic
15 plausibility for a risk factor?

16 A. No.

17 Q. And what Mr. Restaino was discussing with you in
18 connection with this paper were risk factors.
19 Correct?

20 A. Yes.

21 Q. Now, if we could go to Table II of the exhibit.

22 Now, Dr. Neel, you asked several times or
23 pointed several times to the idea of separating out
24 risk factors based on subtype of ovarian cancer.

25 Correct?

1 A. Yes.

2 Q. Does Table II on page 20 of the Reid paper in
3 fact do that?

4 A. Yes.

5 Q. And, so, if we look across the top, it lists
6 five subtypes of ovarian cancer. Correct?

7 A. Correct.

8 Q. Now, let's look at the left-hand column of the
9 paper. There is a title there that is "established
10 risk factor." Correct?

11 A. Yes.

12 Q. Please take a look at the established risk
13 factors identified by Reid in his paper in the
14 left-hand column. Do you see "talc use" there?

15 A. No.

16 Q. Now, let's go to Exhibit A 104, please.

17 Mr. Restaino asked you about the PDQ from the
18 NCI for asbestos. Correct?

19 A. Yes.

20 Q. But there is a PDQ for ovarian cancer, isn't
21 there?

22 A. Yes, there is.

23 Q. Let's take a look at what the PDQ for ovarian
24 cancer says about perineal talc use on page 13.

25 It says:

1 "The weight of evidence does not support an
2 association between perineal talc exposure and an
3 increased risk of ovarian cancer."

4 Correct?

5 A. Correct.

6 MS. SHARKO: No more questions. Thank you.

7 THE COURT: Thank you. You are excused,
8 Dr. Neel.

9 (Witness excused.)

10 THE DEPUTY CLERK: All rise.

11 (Court adjourned at 2:50 p.m.)

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I N D E X

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C E R T I F I C A T E

PURSUANT TO TITLE 28, U.S.C., SECTION 753, THE
FOLLOWING TRANSCRIPT IS CERTIFIED TO BE AN ACCURATE
TRANSCRIPTION OF MY STENOGRAPHIC NOTES IN THE
ABOVE-ENTITLED MATTER.

S/Vincent Russoniello
Vincent Russoniello, CCR
Certificate No. 675

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